Directive 98/8/EC concerning the placing biocidal products on the market

Inclusion of active substances in Annex I or IA to Directive 98/8/EC

Assessment Report

Disodium tetraborate

Product-type 8
(Wood preservative)

20 February 2009

Annex I – the Netherlands

Disodium tetraborate (PT 8)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 20 February 2009 in view of its inclusion in Annex I to Directive 98/8/EC

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1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of disodium tetraborate as product-type 8 (wood preservative), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Disodium tetraborate (CAS no. 1330-43-4, 12267-73-1 and 1303-96-4) was notified as an existing active substance, by Rio Tinto Minerals and Etimine s.a. in a joined notification, hereafter referred to as the applicant, in product-type 8.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 7(1) of that Regulation, the Netherlands was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for disodium tetraborate as an active substance in Product Type 8 was 28 March 2004, in accordance with Annex V of Regulation (EC) No 2032/2003.

On 27 March 2004, the Netherlands competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 24 September 2004.

On 7 July 2006, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 25 July 2006. The competent authority report included a recommendation for the inclusion of disodium tetraborate in Annex I to the Directive for product-type 8.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 17 October 2006. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Commission. Revisions agreed upon were presented at technical and competent authority

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[1] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

[2] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

meetings and the competent authority report was amended accordingly.

On the basis of the final competent authority report, the Commission proposed the inclusion of disodium tetraborate in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 20 February 2009.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 20 February 2009.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include disodium tetraborate in Annex I to Directive 98/8/EC for product-type 8. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in product-type 8 that contain disodium tetraborate. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website[3], shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Directive 98/8/EC, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Overall conclusion in the context of Directive 98/8/EC

The overall conclusion from the evaluation is that it may be expected that there are products containing disodium tetraborate for the product-type 8, which will fulfil the requirements laid down in Article 5 of Directive 98/8/EC. This conclusion is however subject to:

i. compliance with the particular requirements in the following sections of this assessment report,

ii. the implementation of the provisions of Article 5(1) of Directive 98/8/EC, and

iii. the common principles laid down in Annex VI to Directive 98/8/EC.

Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

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[3] http://ec.europa.eu/comm/environment/biocides/index.htm

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Identity of the active substance

Disodium tetrahydrate is notified in 3 manifestations:

- Disodium tetraborate anhydrous
- Disodium tetraborate pentahydrate
- Disodium tetraborate decahydrate

The CAS no. of disodium tetraborate anhydrous used in this CA-report is 1330-43-4
The CAS no. of disodium tetraborate pentahydrate used in this CA-report is 12267-73-1
The CAS no. of disodium tetraborate decahydrate used in this CA-report is 1303-96-4

The EC no. of each of the disodium tetraborates used in this CA-report is 215-540-4

The minimum purity data presented by the notifier do not comply with impurity data and tests with the active substance. Based on impurity data and tests with the active substance, the minimum purity specification proposed by the RMS is 99.0% (w/w) for both manufacturers and for all hydration forms (expressed as $Na_2B_4O_7.xH_2O$, where $x = 0$, 5 or 10).
There are no (eco)toxicologically relevant impurities.

Physical and chemical properties of the active substance

Disodium tetraborates (anhydrous, pentahydrate, decahydrate) are white, odourless solids. No melting point can be defined for disodium tetraborate pentahydrate and decahydrate because of decomposition of the active substance. When disodium tetraborate decahydrate is heated, it gradually loses water of crystallisation, first forming the pentahydrate, and on further heating forms disodium tetraborate anhydrous.

The water solubility, dissociation constant, partition coefficient, and surface tension for disodium tetraborates as such cannot be determined because disodium tetraborates are converted into boric acid/borate upon dissolution in water:

anhydrous: $Na_2B_4O_7 + 7\ H_2O = 2\ NaB(OH)_4 + 2\ B(OH)_3$.

pentahydrate: $Na_2B_4O_7.5H_2O + 2\ H_2O = 2\ NaB(OH)_4 + 2\ B(OH)_3$.

decahydrate: $Na_2B_4O_7.10H_2O = 2NaB(OH)_4 + 2B(OH)_3 + 3H_2O$.

The water solubility, dissociation constant, partition coefficient, and surface tension found will be the ones for an equivalent amount of boric acid in the presence of sodium ions.

Boric acid is a Lewis acid (hydroxide ion acceptor) rather than a Brønsted acid (proton donator). For this purpose the formula for boric acid is best written as $B(OH)_3$.

At low boron concentrations ($B \leq 0.025$ M) the following equilibrium is found:

$B(OH)_3 + 2H_2O \leftrightarrow B(OH)_4^- + H_3O^+$ with a dissociation constant pKa = 9.0 at 25°C

In dilute aqueous solutions ($B \leq 0.025$ M) boric acid exists as undissociated boric acid $B(OH)_3$ at $pH < 7$, at $pH > 11$ the metaborate ion $B(OH)_4^-$ becomes the main species in solution. At in between values (pH 7-11) both species are present.

At higher boron concentrations (B > 0.025 M) an equilibrium is formed between $B(OH)_3$, polynuclear complexes of $B_3O_3(OH)_4^-$, $B_4O_5(OH)_4^{2-}$, $B_3O_3(OH)_5^{2-}$, $B_5O_6(OH)_4^-$ and $B(OH)_4^-$. In short: $B(OH)_3 \leftrightarrow$ polynuclear anions $\leftrightarrow B(OH)_4^-$. In acid solution at pH<5, boron is mainly present as $B(OH)_3$ and in alkaline solution at pH>12.5, boron is mainly present as $B(OH)_4^-$. At in between values (pH 5-12) polynuclear anions are found as well as $B(OH)_3$ and $B(OH)_4^-$.

In the presence of metal ions (e.g. Na, Mg, Ca) ion-pair complexes are formed, which further reduce the undissociated boric acid concentration:

$M^{n+} + B(OH)_4^- \leftrightarrow MB(OH)_4^{(n-1)+}$

These ion pair complexes are expected to be present in solutions of disodium tetraborates, disodium octaborate and buffered solutions of boric acid and boric oxide.

The melting point for disodium tetraborate anhydrous is 737°C. A boiling point is not applicable for all disodium tetraborates. Relative density is 2.354 at 26°C for anhydrous form, 1.860 at 22°C for pentahydrate and 1.74 at 23°C for decahydrate. Vapour pressure and Henry's law constant are not applicable, because the melting point lies above 300°C and at ambient temperature vapour pressure is expected to be less than 10^{-5} Pa. No reliable data are available for flammability of the active substance. Flash point, surface tension and viscosity are not applicable. The active substance has no explosive and no oxidising properties.

Analysis of the active substance as manufactured
There are no methods to determine the active substance as manufactured or in the formulation. Instead, analytical methods are developed to determine the B_2O_3 and Na_2O content in boron based compounds.

<u>Soil</u>
Total boron can be extracted from soil by hot acid extraction with HNO_3 and HCl under reflux or by microwave digestion with HNO_3 and HF, with addition of HCl and H_2O_2 when needed. Several extraction methods are used to estimate the bioavailable boron fraction, of which the hot water soluble extraction is the most widely used.

<u>Water</u>
Boron can be detected in aqueous solutions by spectrophotometry after reaction with azomethine-H, or by ICP-AES.

<u>Air</u>
No data submitted. No data necessary.

Summary information on the identity and physico-chemical properties and analytical methods of disodium tetraborate can be found in Appendix I to this document (List of Endpoints).

2.1.2. Intended Uses and Efficacy

Product type and field of use envisaged

Main group 2:	preservatives
Product type 8:	wood preservative

Disodium tetraborate is intended to be used as a preventive and curative wood preservative for wood and construction timbers in Use Classes 1, 2, 3 and 4a according to CEN 335-1 standard.

User

Industrial, Professional, Non-professional

Function
Fungicide and/or insecticide

Application
Products are applied by vacuum pressure, dipping, injection, spraying/deluge or brushing.

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling

It is proposed to classify borates with reproduction category 2 and assign risk phrases R60-61. This is in line with the proposal of the EU commission working group of specialised experts in the field of reproduction toxicology (2004). Disodium tetraborates are irritating to the eye (R36).

Proposed classification for the active substance disodium tetraborate

Class of danger	T
R phrases	R36 R60-61

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

The toxicokinetics and toxicological effects of boric acid, disodium tetraborate, boric oxide (B_2O_3) and disodium octaborate tetrahydrate are likely to be similar on a boron equivalents basis. Therefore, the data obtained from studies with different borates can be read across in the human health assessment for each individual substance.

2.2.1.1. Hazard assessment

Toxicokinetics
Absorption of borates via the oral route is nearly 100%. For the respiratory route also 100% absorption is assumed. Dermal absorption through intact skin is very low. For risk assessment of borates a dermal absorption of 0.5% is used as a reasonable worst case approach. In the blood boric acid is the main species present. Boric acid is not further metabolised. Boric acid is distributed rapidly and evenly through the body, with concentrations in bone 2-3 higher than in other tissues. Boron is excreted relatively rapidly with elimination half-lives of 1h in

the mouse, 3h in the rat and 21h in humans, and has low potential for accumulation. Boric acid is mainly excreted in the urine.

Acute toxicity
Disodium tetraborate and other borates are of low acute toxicity: LD_{50} oral rat > 2000 mg/kg; LD_{50} dermal rat > 2000 mg/kg; LC_{50} inhalation rat > 2 mg/l (highest attainable concentration).

Irritation and Corrosivity
Disodium tetraborate is not a skin irritant. Disodium tetraborate is an **eye irritant**.

Sensitization
No signs of skin sensitization were observed in Buehler method skin sensitization tests with Disodium tetraborate or other borates and no evidence of skin sensitization in humans exposed occupationally to borates has been reported. Disodium tetraborate needs not to be classified as a skin sensitizer.

Repeated dose toxicity
In the repeated dose studies with mouse and rat (and dog although studies are not acceptable), consistently effects on the testes and on blood parameters were found. In the 90 days study in the mouse and the 2 year study in the rat the animals appeared to be more sensitive to the effects on the haematopoietic system than on the testes. Similar results were obtained from studies with disodium tetraborates. The 2 years feeding study with boric acid in rats yielded an overall NOAEL (100 mg/kg bw, equal to 17.5 mg B/kg bw/day), based on reduction bodyweight, clinical sign of toxicity, in males testicular atrophy and reductions in red cell volume and Hb at a dose of 334 mg/kg bw/day (58.5 mgB/kg bw/day). This finding is supported by the study with disodium tetraborate decahydrate.

Genotoxicity
Disodium tetraborate has no genotoxic potential.

Carcinogenicity
In carcinogenicity studies in mice and rats no evidence of a carcinogenic effects of boric acid or sodium tetraborate decahydrate was observed. It is concluded that disodium tetraborate is unlikely to pose a carcinogenic risk.

Reproductive toxicity
Teratogenicity
The most sensitive species for developmental effects appears to be the rat. The NOAEL for embryotoxic/teratogenic effects of boric acid was 55 mg/kg bw/day (9.6 mg B/kg bw/day), based on a reduction in mean foetal body weight/litter and an increased incidence in short rib X111, which is considered a variation, at 76 mg/kg bw/day (13.3 mg B/kg bw/day). The relevance of the observed developmental effects for humans is not clear.

Fertility
In a multigeneration reproduction toxicity study in the rat with boric acid severely impaired reproductive potency was observed at 336 mg/kg bw/day. At this dose also marked reductions (70%) in relative testes weights were observed. At lower doses no reproductive effects or effects on testes weight were observed. These findings suggest that a reduction in testes weight will result in an impaired fertility. Since this study was seriously flawed, no definitive conclusions on the effects of boron on fertility in the rat can be drawn. Other repeated dose studies in several animal species have consistently demonstrated that the testis is a primary target organ for boron. Based on the data from the 2 years feeding study with boric acid in

rats, the overall NOAEL for fertility is therefore 100 mg/kg bw/day, equal to 17.5 mg B/kg bw/day. This conclusion is supported by the study with disodium tetraborate decahydrate.

Neurotoxicity
No neurotoxic studies were available for the present evaluation. CNS depression was observed in poisoning cases in humans. Apart from the CNS effects that occur at these very high doses there are no indications that boric acid or other borates have neurotoxic properties. No neurotoxicity studies are required.

Human data
It has been suggested that the potential lethal oral dose of boric acid is 3-6g in children and 15-20 g for adults. However, lethal doses are not well documented. Acute effects may include nausea, vomiting, gastric discomfort, skin flushing, excitation, convulsions, depression and vascular collapse. Multiple exposure (high levels > 1g) results in various symptoms which may appear singly or together and include dermatitis, alopecia, loss of appetite, nausea, vomiting, diarrhoea, and focal or generalised central nervous system irritation or convulsions.
Infants aged from 6 to 16 weeks who ingested sodium tetraborate at doses of about 0.98 g boric acid/day for periods of 4 to 12 weeks showed convulsions, generalised seizures and focal seizures.
Workers exposed occupationally to borax dust at concentrations of about 4 mg/m^3 reported eye irritation, dry mouth, nose or throat, sore throat, acute and chronic respiratory irritation and productive cough.

Effects on human reproduction
In human epidemiological cohort study in Turkey no effects on reproduction were observed in populations exposed to high levels of boron through drinking water. However, this conclusion was based on the number of children born over a period of 15 years. Other endpoints such as time to pregnancy and number of miscarriages were not included. In a study in the USA, the fertility of male workers of a borax mine was studied. The study revealed that the workers exposed to low (<0.82 mg/m^3) or high (>5.05 mg/m^3) levels of boron in dust fathered more live births than was estimated on the basis of the data of the US general population. The extent to which the workers are comparable to the US general population however was not clear. Also in this study other endpoints such as time to pregnancy were not established.

2.2.1.2. Critical endpoints and assessment factors

Overall NOAEL
The toxicological data base reveals that the major targets for toxicity of borates are the testes and the blood. In the repeated dose studies with mouse, rat and dog, consistently effects on the testes and on blood parameters were found. In a 90 days study in the mouse the animals appeared to be more sensitive to the effects on the haematopoietic system than on the testes. In the rat effects on both the testes and on the blood were observed at dose levels of 334 mg boric acid/kg bw/day. The NOAEL in this study was 100 mg/kg bw/day (17.5 mg B/kg bw/day). Similar results were obtained from studies with disodium tetraborate decahydrate at equimolar doses of boron. Based on the NOAEL for embryotoxic/teratogenic effects of boric acid of 55 mg/kg bw/day (9.6 mg B/kg bw/day) the overall NOAEL is 9.6 mg B/kg bw/day.

Total assessment factor
The available information on kinetics and dynamics does not allow refinement of the standard assessment factors (10 for interspecies variation and 10 for intraspecies variation).

There are indications that the sensitivity for the effects on the testes does not differ markedly between subchronic and chronic exposure. Therefore the application of an additional assessment factor for extrapolation from subchronic to chronic exposure is not required.

ADI (acceptable daily intake) and ARfD (acute reference dose).

The borates will be used as wood preservatives. The borates are not used on wood products that are used for food preparation or feeding stuff. Furthermore finished wood products containing borates and manufactured for structural and building material are not appropriate to be used and would not be used to make products that would come in to contact with food or feeding stuff. Therefore the derivation of an ADI and ARfD is considered not necessary.

Drinking water limit

Based on the overall NOAEL (9.6 mg boron/kg bw/day), which was found in the developmental study in the rat and the overall assessment factor of 100, a tolerable daily intake (TDI) of 9.6/100= 0.096 mg/kg bw/day can be established. If 10% of the TDI is allocated to boron in drinking water, and assuming that an adult weighs 60 kg and consumes 2 litre drinking water per day, a drinking water guideline value 0.29 mg/L can be derived.

The WHO established in 1998 a drinking water guideline value of 0.5 mg/L, based on an overall NOAEL of 9.6 mg boron/kg bw per day from a developmental toxicity study in the rat, and a total assessment factor of 60. Drinking water on average contains 0.1-0.3 mg boron per litre, while in some regions much higher concentrations have been measured (EHC 204, 1998). Boron in the soil and aquatic environment is predominantly originating from natural weathering of rock and sea water evaporation (EHC 204, 1998). Accordingly, human exposure to boron will probably not have changed significantly over time.

It is clear that a drinking water limit of 0.29 mg/L, as estimated on the basis of the present toxicological data set, will generally not be exceeded.

AOEL (acceptable operator exposure level).

Using the standard assessment factor of 100 (10 for interspecies- and 10 for intraspecies variation) an oral AOEL of 0.096 mg B/kg bw/day can be derived based on the NOAEL for embryotoxic/teratogenic effects of boric acid of 9.6 mg B/kg bw/day. Based on the NOAEL of 17,5 mg B/kg bw/day in a 2-year study in the rat and an assessment factor of 300 due to serious effects and based on the NOAEL of 21.8 mg B/kg bw/day in a teratogenicity study in the rabbit and an assessment factor of 300 due to serious effects AOEL values can be derived of 0.06 and 0.07 mg B/kg bw/day, respectively. For the risk assessment, a rounded (systemic) AOEL value of 0.1 mg B/kg bw/day was used for disodium tetraborates, even though values of 0.06 and 0.07 mg B/kg bw/day could be derived from the critical effects.

MOE (margin of exposure)

Professional users.

For the risk assessment of borates the systemic NOAEL of 9.6 mg/kg bw/day will be used. A MOE of 100 would be considered acceptable, on the basis of the standard assessment factors of 100 (10 x 10) for interspecies and intraspecies variability.

Non-professional users

The developmental studies are considered to be the most relevant for the risk characterization of non-professional users of borates. A MOE of 100 with respect to the NOAEL of 9.6 mg B/kg bw/day from the developmental toxicity study in the rat is considered acceptable.

2.2.1.3. Risk characterisation

Professional users

For calculating the exposure for the 7 processes of professional users, models in the TNsG on human exposure are used.

1. Vacuum pressure impregnation, normal treatment
2. Vacuum pressure impregnation, termite treatment
3. Double vacuum pressure, normal treatment
4. Double vacuum pressure, termite treatment
5. Dipping, normal treatment
6. Automatic spraying / deluge, normal treatment
7. Professional spraying on-site, normal treatment

Based on the AOEL approach and MOE approach it can be concluded that adverse health effects for the unprotected professional user due to the combined dermal and respiratory exposure of disodium tetraborate, as a result of the 7 processes, cannot be excluded. Using standard protective gloves, coverall and dust masks for mixing and loading and protective gloves and coverall for application is sufficient enough to reduce the exposure to get the risk indices <1 and the MOE's >100 for all of the 7 processes.

Non-professional users.

For calculating the exposure for the 2 processes of non-professional users, models in the TNsG on human exposure are used.

1. Spraying
2. Brushing

Based on the AOEL approach and MOE approach it can be concluded that adverse health effects for the unprotected non-professional user due to the combined dermal and respiratory exposure of disodium tetraborate, as a result of **spraying** and **brushing** can be excluded.

Indirect exposure as a result of use

For calculating the indirect exposure for 3 situations the reference scenarios in the user guidance TNsG (2002) are used.

1. Exposure during cutting and sanding by non-professionals, single exposure
2. Exposure during cutting and sanding by professionals, repeated, daily exposure
3. Exposure of a child playing on playground structure outdoors, repeated, daily exposure

Exposure due to chewing of wood chippings is considered negligible, as well as the exposure by inhaling volatilised residues indoor.

Based on the AOEL and MOE approach it can be concluded that no adverse health effects for the non-professional user and the professional user due to indirect exposure are expected.

For a child playing on a playground structure outdoors a health risk as a consequence of exposure to borates can be excluded.

2.2.2. Environmental Risk Assessment

Once borates are released to the environment, the predominant species is un-dissociated boric acid. For practical reasons boric acid and other borates are usually expressed on the basis of boron.

Boron is a naturally occurring element that is essential to a variety of organisms. Because of boron being present in natural environments, the background concentrations should be taken into account when deriving PNEC's. Boron concentrations in freshwater systems rarely exceed 1.0 mg B/L and are usually < 0.1 mg B/L. A recent review of European monitoring data report ranges of < 0.001 to 7.5 mg B/L, the mean 95-percentile concentration over 15 European countries ranges from 0.017 mg B/L in the United Kingdom to 0.632 mg B/L in

Germany. Oceans have a natural level of boron of about 5 mg/L. Boron concentrations in soil are highly variable, ranges are 4 to 200 mg/kg, mostly as the *unavailable* earth mineral tourmaline and usual levels are 45-124 mg/kg dwt, based on observations in the United States. Boron levels in European groundwaters ranged for Italy and Spain from 0.5 to 1.5 mg/litre (mean boron concentrations); up to approximately 0.6 mg boron/litre in the Netherlands and United Kingdom, and levels in approximately 90% of samples in Denmark, France, and Germany were found to be below 0.3, 0.3, and 0.1 mg boron/litre, respectively. In the following sections, all data refer to added boron, unless stated otherwise.

2.2.2.1. PNEC derivation

The notifier proposed to base the Risk Assessment on total PNEC (i.e. including background concentrations). He argues that the background boron concentration influences a number of biological/ecological processes (e.g. optimal concentration ranges, acclimation/adaptation, and field community responses), and is crucial for the derivation of ecological relevant PNEC values.

The RMS partly agrees with this point of view but considers that other arguments have to be taken into account:

- In the added risk approach both the "Predicted Environmental Concentration" (PEC) and the "Predicted No Effect Concentration" (PNEC) are expressed as B added by man, resulting in an “added Predicted Environmental Concentration” (PEC_{add}) and “added Predicted No Effect Concentration” ($PNEC_{add}$), respectively. The use of the added risk approach (a method that in principle can be used for all naturally occurring substances) implies that only the anthropogenic amount of a substance, i.e. the amount added to the natural background concentration, is considered to be relevant for the effects assessment of that substance.
- There is inadequate knowledge of the natural Boron concentrations in water, sediment and soil.
- There is insufficient knowledge to incorporate bioavailability.
- No studies are available that indicate acclimatization and adaptation effects to the sensitivity of species to Boron - with the exception of deficiency occurring in some fish and plant studies.
- There is no information that Boron is essential to all biota.

The RMS therefore prefers to conduct the risk assessment on *added concentrations*.

Aquatic compartment

Based on the lowest NOEC of 1.8 mg B/L and an assessment factor of 10 the $PNEC_{add,aquatic}$ for freshwater systems is set to **0.18 mg B/L**. Using equilibrium partitioning the $PNEC_{add,sed}$ is set to **0.24 mg B/kg wwt**. As both PEC_{sed} and $PNEC_{sed}$ values are based on equilibrium partitioning, no further assessment of the risk was performed.

Sewage treatment plants (STPs)

Based on a submitted microbial inhibition test with micro-organisms in activated sludge, a $PNEC_{add,STP}$ of **1.8 mg B/L** was calculated, based on a NOEC of 17.5 mg B/L and applying an assessment factor of 10.

Air

No toxicity data for air were available. Therefore, a $PNEC_{air}$ was not calculated.

Terrestrial compartment

The $PNEC_{add,terrestrial}$ should be regarded as the concentration that may be *added* to the background without inducing adverse effects on the terrestrial ecosystem. It is implicitly assumed that the background concentration itself does not induce a toxic effect and that the background concentration is sufficient to meet the natural demands of the organisms and that there is no risk for deficiency.

The **$PNEC_{add,terrestrial}$** is set to **0.4 mg B/kg dwt soil,** equivalent to **0.35 mg B/kg wwt soil**. The applicability of a low $PNEC_{add,terrestrial}$ should be judged in the light of sensitive plant species instead of being focussed solely on tolerant species.

Non compartment specific effects relevant to the food chain (secondary poisoning)

Boron is not bioconcentrated or bioaccumulated along the food chain in both aquatic and terrestrial ecosystems.

2.2.2.2. Exposure and risk characterisation

The environmental exposure assessments have been taken from the OECD Emission Scenario Document Number 1, 2 and 3, Emission Scenario Documents on Wood Preservatives (OECD, 2003) using boric acid as the representative boron compound. Boron is released into the environment during processing, from treated timber in storage after industrial treatment, during end use (in-service period) and during and after in-situ treatment of wood. Releases can enter the aquatic compartment (incl. sediment), soil (incl. groundwater) and to a lesser degree air, depending on the scenario. Applications involve the normal application and application against termites. Application against termites is only taken into account if it is considered relevant for certain scenarios.

The following applications and in-service uses are recognized:

• Processing/storage:	Vacuum pressure[1]; Double vacuum[1]; Automated dipping/industrial deluge; Automated spraying
• In-situ applications:	Noise barrier; Bridge; Fence; House; Transmission pole
• Wood in service[1]:	Noise barrier; Fence; House cladding; Transmission pole; Fence post

[1] *scenarios relevant for applications against termites*

No emissions to the environment are expected during service life for Use Class 1 (timber under cover including indoor joinery (preventive)) and Use Class 2 (timber under cover including indoor roofing timbers – risk of wetting (preventive)). Therefore Use Class 1 and 2 is considered not to lead to unacceptable risk to the environment.

The risk assessment for the industrial application phase (processing/storage), the *in-situ* treatment, and wood in service (Use class 3 and 4a) are considered below.

As to the waste stage the ESD states the following: “Waste treatment: at this stage the unused wood preservative products or the out-of-service treated wood is disposed of with waste. Waste treatment may consist of incineration or landfill dumping. Releases during these processes are considered through leaching models and release of non-degraded substances during incineration, especially heavy metal oxides. Disposal of wastes from treatment plants or disposal of treated wood after service do not fall under the scope of this ESD document. Waste wood, waste wood dust, protection foil, cleaning solvents, used cans and unused product should be disposed of according to national waste disposal regulations”.

Aquatic Environment (fresh water)

PEC/PNECs are > 1 (in the range of 7.9 to-79) for the in-situ treatments on and in service period of treated bridges over ponds, and a risk is expected. The other uses (processing, storage and wood in service, such as noise barriers) are considered as safe with respect to the risks for surface water.

Aquatic Environment (sediment)
As the $PNEC_{add,sed}$ and the $PEC_{add,sed}$ both are based on equilibrium partitioning, risks found in the aquatic risk assessment related to the bridge over pond scenario also will result in risks for the sediment. The other uses (processing, storage and wood in service, such as noise barriers) are considered as safe with respect to the risks for sediment.

Sewage treatment plants (STPs)
Industrial application and use of treated wood as a noise barrier may result in emission of boric acid to a STP. In all cases, a risk for micro-organisms in the STP is not expected (PEC/PNEC < 1).

Assessment of drinking water criterion
According to Directive 98/83/EC Annex I, part B, the limit value for boron in water is 1 mg/L. This value is exceeded in the scenario for *in-situ* treatment and treated wood in service of a bridge over pond (UC3) (TIME2 PEC values ranging between 3.34 and 14.3 mg B/l) and the PEC/PNEC is also > 1. European monitoring data (Wyness et al. 2003) report ranges of < 0.001 to 7.5 mg B/L, the mean 95-percentile concentration over 15 European countries ranges from 0.017 mg B/L in the United Kingdom to 0.632 mg B/L in Germany. This means that disodium tetraborate(in situ applied and in service) in treated wood of bridges over ponds does **not** comply with the drinking water criteria.

Air
Because of the low vapour pressure, release of borates to air will be minimal. No $PEC_{add,air}$ and $PNEC_{add,air}$ were calculated.

Terrestrial environment
Storage of treated wood after industrial treatment, in-service and in-situ treatment of use class 3 and 4a treated wood will result in emission of boric acid to soil. PEC/PNEC ratios exceed 1 (range 5.1 – 600). Concerning the in-situ treatment of wood and storage of wood after industrial treatment and before shipment reasonable risk mitigation measures are available (see section 3.2 below). The in-service use of treated wood with disodium tetraborate for class 3 and 4a applications will lead to unacceptable risks.

Groundwater
The $PEC_{add,grw}$ is estimated from the $PEC_{add,terrestrial}$ using equilibrium partitioning. The calculated $PEC_{add,grw}$ is evaluated according to the criteria for water that will be used for production of drinking water. The limit value for boron is 1 mg B/L (Directive 98/83/EC Annex I, part B).
The $PEC_{add,grw}$ is above 1 mg B/L in all cases (range: 3.1 - 194) and the use of disodium tetraborate does **not** comply with the drinking water criterion.

Assessment of persistence in soil
Being an inorganic compound, boron does not comply with the persistence criteria of $DT_{90,field}$ < 1 year and DT_{50} at 20°C < 6 months that are laid down in paragraph 85 of Annex VI to the Biocides Directive and in the TNsG on Annex I inclusion. According to the latter, the degradation triggers do not necessarily apply if the active substance is included in Annex I with regard to areas of use where a long lasting service-life of the treated material is essential and it is scientifically demonstrated that under field conditions there is no unacceptable

accumulation in soil (e.g. that the PEC/PNEC < 1 in soil during the service-life of the treated article). The application as a wood preservative can be considered as such. It was shown above in Section 2.9.6 that for all Use Classes the PEC/PNEC ratio is far above 1 (range: 150 – 2244). Disodium tetraborate does not meet the criteria for persistence in soil, and is therefore considered persistent.

2.2.2.3. PBT assessment

Being an inorganic compound, boron does not biodegrade in marine or freshwater and sediments, and should therefore be considered as Very Persistent (VP).
Boron is not bioconcentrated, based on the available data the BCF is < 2000 L/kg wwt.
The chronic NOEC of boron for marine or freshwater organisms is > 0.01 mg B/L and boron is not considered to have endocrine disrupting effects. However, based on toxicological data, boron is classified with Toxic for Reproduction category 2 and assigned risk phrases R60 and R61. Therefore, boron should be considered as fulfilling the criteria for Persistence and Toxicity, but not for Bioaccumulation.
Boron does not fulfil the PBT-criteria. Therefore inclusion in Annex I is not restricted by these criteria.

2.2.3. List of endpoints

In order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

3. DECISION

3.1. Background to the Decision

Disodium tetraborate is requested for inclusion in Annex I as a wood preservative to be used in Use Classes 1, 2, 3 and 4a by professional and non-professional users. Use Classes 4b and 5 are not included in the present assessment and no inclusion can be granted for these uses.

The unconditional inclusion of disodium tetraborate in Annex I can only be granted in case efficacy can be demonstrated for all proposed uses and the proposed uses do not lead to an unacceptable risk for humans and the environment.
A conditional inclusion of disodium tetraborate in Annex I can be granted in case efficacy can be demonstrated and at least one of the proposed uses do not lead to an unacceptable risk for humans or the environment.

The risk assessment for disodium tetraborate is based on a fictitious model product containing 100% disodium tetraborate. Actual products based on disodium tetraborate contain less then 100% disodium tetraborate, other active substances and additives. Therefore the assessment in this report is indicative. The risks of actual products should be assessed at the product authorisation level.

Inclusion of disodium tetraborate in Annex I is feasible for the efficacy, human health and environmental aspect because efficacy is demonstrated for certain applications, a safe use is identified for human exposure when using PPE and for environmental exposure when the treated wood is used for Use Class 1 (wood under cover and fully protected from the weather) and Use Class 2 (wood under cover and fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting for indoor use and/or incidentally getting wet).
For Use Class 3 and 4a the environmental risk assessment is performed according to the TGD and TNsG's, with high PEC:PNEC ratios (PEC/PNEC >>1) as a result.
At product authorisation level extra attention should be paid to potential risks for the environment for Use Classes 3 and 4a.

Methods of analysis:
All necessary methods of analysis for disodium tetraborate are available.

Efficacy:
Pure disodium tetraborate has shown to be effective against fungi (wet rot, dry rot), egg larvae of wood-boring insects and termites, however, the available data do not permit that final conclusions can be drawn concerning efficacy against all the target organisms to be controlled.
Leaching of most of the impregnated boric acid from treated wood can occur within days/months. No information is available about the influence of leaching on the efficacy of the disodium tetraborate product.

Labelling and classification:
Disodium tetraborate has a proposed classification with: 'T' (Toxic), R36 (eye irritant), R60 (may impair fertility) and R61 (may cause harm to the unborn child).

Products containing more then the specific concentration limit of 4.5% of disodium tetraborate anhydrous (30th ATP to Directive 67/548/EEC) will be classified with R60-61 and shall not be authorised for marketing to, or use by the general public.

Products containing more then the specific concentration limit of 6.5% of disodium tetraborate pentahydrate (30th ATP to Directive 67/548/EEC) will be classified with R60-61 and shall not be authorised for marketing to, or use by the general public.

Products containing more then the specific concentration limit of 8.5% of disodium tetraborate decahydrate (30th ATP to Directive 67/548/EEC) will be classified with R60-61 and shall not be authorised for marketing to, or use by the general public.

Human health:
Adverse health effects due to the combined dermal and respiratory exposure to disodium tetraborate can be excluded for the protected professional user using regular PPE, as a result of the proposed uses of the model product based on 100% disodium tetraborate.

No adverse health effects due to indirect exposure are expected for the non-professional user and the professional user.
For a child playing on a playground structure outdoors a health risk as a consequence of exposure to borates can be excluded.

Environment:
Storage:

Unacceptable emissions to soil during storage after industrial treatment are expected. Emissions resulting from storage can for instance be prevented by covering the storage place and/or providing an impermeable storage floor. Under these conditions, the use of disodium tetraborate is considered not to lead to unacceptable risk to the environment.

Service life of wood:

For Use Class 1 and 2, no emissions to the environment are expected during service life of the treated wood. Use Classes 3 and 4a are expected to lead to risks, resulting from emissions to soil (in-service treated fences and posts, noise barriers, transmission poles and wooden houses) and water (Bridge over pond scenario) during the service life (see table 3.1-1).

In-situ treatment:

Emissions to soil and water during *in-situ* treatment with disodium tetraborate are expected to lead to risks. Prevention of losses to soil or water during treatment can be prescribed to reduce the PEC/PNEC ratios to blow 1.

Table 3.1-1 Summary of environmental risk of disodium tetraborate.

	Fresh water environment	Sediment	Sewage treatment plants	Drinking water criterion	Persistency in sediment	Air	Terrestrial environment	Groundwater	Persistency in soil
Industrial treatment	-	-	-	-	-	-	n.a.	n.a.	n.a.
Storage of industrial treated wood	-	-	-	-	-	-	$+^a$	$+^a$	$+^a$
Wood in service	-	-	n.a.	-	-	-	+	+	+
In-situ treatment	$+^b$	+	n.a.	+	-	-	+	+	+

\- no risk expected
\+ risk expected
n.a. not applicable
[a] risk reduction possible, for instance storage on hard standing and collection of rainwater
[b] only relevant for in-situ treatment of bridges over ponds

3.2. Decision regarding Inclusion in Annex I

The active substance disodium tetraborate shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type 8 (wood preservative), subject to the following specific provisions:

a) The active substance disodium tetraborate shall have a minimum purity of 99.0% expressed as $Na_2B_4O_7$ (anhydrous). The active substance disodium tetraborate pentahydrate shall have a minimum purity of 99.0% expressed as $Na_2B_4O_7.5H_2O$. The active substance disodium tetraborate decahydrate shall have a minimum purity of 990 g/kg expressed as $Na_2B_4O_7.10H_2O$.

Member States shall ensure that authorisations are subject to the following conditions:

(1) Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for

product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means.

(2) In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

3.3. Elements to be taken into account by Member States when authorising products

The risk assessment based on the dummy product showed that the use of disodium tetraborate in Use Class 1 and 2 is safe. For the use of that product in Use Class 3 and 4a unacceptable risks were identified in the soil and water compartment due to spills during in-situ treatment and from the in-service leaching of boric acid to soil from treated wood. Disodium tetraborate shall not be authorized in wood preservative products for Use Class 3 and 4a if it has been concluded in the means of comparative assessment that there is a sufficient number of active substances for same use purposes for Use Class 3 and 4a with significantly lower risk and without unacceptable effects.

Disodium tetraborate was intended to be used by industrial, professional and non-professional users. However, disodium tetraborate was found to be ‘Toxic for reproduction category 2 (R60-61)’. Products containing more then the specific concentration of 4.5% disodium tetraborate anhydrous will be classified with R60-61 and, according to article 5 (2) of the Directive, products with this classification shall not be authorised for marketing to, or use by the general public.

Products containing more then the specific concentration of 6.5% disodium tetraborate pentahydrate will be classified with R60-61 and, according to article 5 (2) of the Directive, products with this classification shall not be authorised for marketing to, or use by the general public.

Products containing more then the specific concentration of 8.5% disodium tetraborate decahydrate will be classified with R60-61 and, according to article 5 (2) of the Directive, products with this classification shall not be authorised for marketing to, or use by the general public.

Health effects professional user: The risk characterization for human health is based on a 100% disodium tetraborate product. Actual wood preservatives are based on less then 100% disodium tetraborate and/or have more then one active substance. When authorising such products appropriate measures should be prescribed to protect professional users in such a way that risk indices are below 1.

Storage stage: The risk to the soil compartment following storage on site of industrial impregnated timber is unacceptable. Therefore emission reducing measures should be prescribed, for instance the storing of treated timber on hard impermeable standing and the collecting of rainwater from the storage area to prevent direct losses of boric acid to soil.

Handling and Storage

No special handling precautions are required, but dry indoor storage is recommended. Good housekeeping procedures should be followed to minimise dust generation and accumulation. No specific fire fighting measures are required since disodium tetraborate is not flammable, combustible or explosive. The product is itself a flame retardant.

Suitable container material: paper, cardboard, plastic (polypropylene, high density polyethylene).
Unsuitable container material: base metals.
Polypropylene is not suitable for storage at low temperatures due to the brittleness of this material at low temperatures. Polyethylene should therefore be regarded as the preferred container material for disodium tetraborate.

Emergency measures in case of accident
Inhalation: If symptoms such as nose or throat irritation are observed, remove to fresh air.
In case of contact with eyes: Rinse immediately with plenty of clean water or sterile saline solution for at least 15 minutes. If appropriate, remove contact lenses after 5 minutes rinsing. If symptoms persist, seek medical attention.
Skin contact: No treatment necessary because non-irritating.
Ingestion: Swallowing small quantities (one teaspoon) will cause no harm to healthy adults. If larger amounts are swallowed, give two glasses of water to drink and seek medical attention.
Avoid creation of dust. Use vacuum cleaners wherever possible.

Decontamination
Air: Borates are non-volatile. As a dust borates rapidly settle from the atmosphere.
Water: Borates are naturally occurring minerals and are present in surface and underground waters. Borates are rapidly dissolved in water and will disperse with dilution. Removal at low concentrations is unnecessary. Where water containing high levels of borates can be captured precipitation with lime can be used to reduce boron levels to the 100 ppm range. Treatments with boron specific ion exchange resins and activated carbon are also possible.
Soil: Borates are naturally found in rocks and soil and are an essential micronutrient for all plant growth. Contaminated soil can be leached with water or acid to reduce boron levels.

Waste Management
Prevention of waste and unintended environmental releases is practiced by most, if not all operations. Storage of treated products is covered so as to prevent leaching and run-off. Small quantities can usually be disposed to landfill sites. No special disposal treatment is required, but local authorities should be consulted about any specific local requirements. Tonnage quantities of products are not considered appropriate for landfills. Such products should, if possible, be used for an appropriate application.

Unintended side effects
Borates are essential micronutrients for all plant life but at high levels they are phytotoxic.

Combustion Products
Fused borate, glass and water.

3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the inclusion of disodium tetraborate in Annex 1 to Directive 98/8/EC.

3.5. Updating this Assessment Report

This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of disodium tetraborate in Annex I to the Directive.

Appendix I: List of endpoints

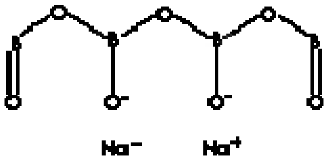
Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Common Name)	Disodium tetraborate anhydrous Disodium tetraborate pentahydrate Disodium tetraborate decahydrate
Function (*e.g.* fungicide)	Fungicide, insecticide

Rapporteur Member State	The Netherlands

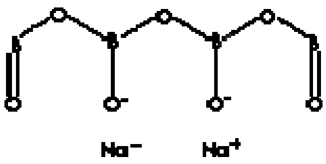
Identity for disodium tetraborate anhydrous (Annex IIA, point II.)

Chemical name (IUPAC)	disodium tetraborate anhydrous
Chemical name (CA)	disodium tetraborate anhydrous
CAS No.	Several CAS numbers exist for the same compound. • disodium tetraborate anhydrous or boric acid disodium salt, CAS 1330-43-4 • orthoboric acid sodium salt, CAS 13840-56-7, is an unspecified sodium salt and is listed under disodium tetraborate anhydrous. • tetraboron disodium heptaoxide hydrate CAS 12267-73-1, is an unspecified hydrate salt and is listed under disodium tetraborate anhydrous. • disodium tetraborate anhydrous, CAS 12447-40-4. For the present CA-report, only disodium tetraborate anhydrous, CAS no 1330-43-4 is used. The other CAS numbers are not assessed in this CA-report.
EC No.	Several EC numbers exist for the same compound. • disodium tetraborate anhydrous or boric acid disodium salt, EC 215-540-4 • orthoboric acid sodium salt, EC 237-560-2, is an unspecified sodium salt and is listed under disodium tetraborate anhydrous. • tetraboron disodium heptaoxide hydrate, EC 235-541-3 is an unspecified hydrate salt and is listed under disodium tetraborate anhydrous. For the present CA-report, only disodium tetraborate anhydrous, EC 215-540-4 is used. The other EC numbers are not assessed in this CA-report.
Other substance No.	None
Minimum purity of the active substance as manufactured (g/kg or g/l)	Based on impurity data and tests with the active substance, the minimum purity specification proposed by the RMS is 99.0% (w/w) expressed as $Na_2B_4O_7$

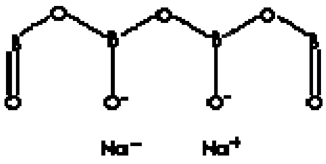
	(anhydrous) for both manufacturers.
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	no additives no (eco)toxicologically relevant impurities
Molecular formula	general formula $Na_2B_4O_7$; another frequently used formula is $Na_2O.2B_2O_3$ (water free).
Molecular mass	201.22
Structural formula	

Identity for disodium tetraborate pentahydrate (Annex IIA, point II.)

Chemical name (IUPAC)	disodium tetraborate pentahydrate
Chemical name (CA)	disodium tetraborate pentahydrate
CAS No.	Several CAS numbers exist for the same compound. • disodium tetraborate pentahydrate or borax pentahydrate, CAS 12179-04-3. • disodium tetraborate pentahydrate, CAS 12267-73-1 • disodium tetraborate pentahydrate, CAS 12045-88-4 • disodium tetraborate pentahydrate, CAS 11130-12-4 For the present CA-report, only disodium tetraborate pentahydrate, CAS no is 12179-04-3 is used. The other CAS numbers are not assessed in this CA-report.
EC No.	Two EC numbers exist for the same compound. • disodium tetraborate pentahydrate or borax pentahydrate, EC 215-540-04. • disodium tetraborate pentahydrate, EC 235-541-3. For the present CA-report, only disodium tetraborate pentahydrate, EC no is 215-540-4 is used. The other EC numbers are not assessed in this CA-report.
Other substance No.	None
Minimum purity of the active substance as manufactured (g/kg or g/l)	Based on impurity data and tests with the active substance, the minimum purity specification proposed by the RMS is 99.0% (w/w) expressed as $Na_2B_4O_7.5H_2O$ for both manufacturers.
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	no additives no (eco)toxicologically relevant impurities
Molecular formula	general formula $Na_2B_4O_7.5H_2O$; another frequently used formula is $Na_2O.2B_2O_3.5H_2O$.
Molecular mass	291.296

Structural formula	

Identity for disodium tetraborate decahydrate (Annex IIA, point II.)

Chemical name (IUPAC)	disodium tetraborate decahydrate
Chemical name (CA)	disodium tetraborate decahydrate
CAS No.	Two CAS numbers exist for the same compound. • disodium tetraborate decahydrate or borax decahydrate CAS 1303-96-4. • disodium tetraborate decahydrate CAS 13840-56-7. For the present CA-report, only disodium tetraborate decahydrate, CAS no is 1303-96-4 is used. The other CAS numbers are not assessed in this CA-report.
EC No.	Several EC numbers exist for the same compound. • disodium tetraborate decahydrate or borax decahydrate, EC 215-540-04. • disodium tetraborate decahydrate, EC 235-541-3 • disodium tetraborate decahydrate, EC 271-536-2 For the present CA-report, only disodium tetraborate decahydrate, EC no is 215-540-4 is used. The other EC numbers are not assessed in this CA-report.
Other substance No.	None
Minimum purity of the active substance as manufactured (g/kg or g/l)	Based on impurity data and tests with the active substance, the minimum purity specification proposed by the RMS is 99.0% (w/w) expressed as $Na_2B_4O_7.10H_2O$ for both manufacturers.
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	no additives no (eco)toxicologically relevant impurities
Molecular formula	general formula $Na_2B_4O_7.10H_2O$ another frequently used formula is $Na_2O.2B_2O_3.10H_2O$.
Molecular mass	381.373
Structural formula	

Physical and chemical properties for disodium tetraborate anhydrous (Annex IIA, point III, unless otherwise indicated)

Melting point (state purity)	Melting point 737 °C at atmospheric pressure, deduced

	from pentahydrate data
Boiling point (state purity)	Not applicable
Temperature of decomposition	At 525/527 °C a phase transition occurs, as deduced from pentahydrate data.
Appearance (state purity)	Solid white odourless powder (purity not stated)
Relative density (state purity)	2.354 at 26 °C (purity 99.0% (w/w) expressed as $Na_2B_4O_7$ (anhydrous)
Surface tension	Not applicable
Vapour pressure (in Pa, state temperature)	Not applicable, because the melting point lies above 300 °C and at ambient temperature vapour pressure is expected to be less than 10^{-5} Pa.
Henry's law constant (Pa m^3 mol $^{-1}$)	Not applicable, because the melting point lies above 300 °C and at ambient temperature vapour pressure is expected to be less than 10^{-}5 Pa.
Solubility in water (g/l or mg/l, state temperature)	pH_ 9.66-9.69: 27.0 g/L at 20.0°C, calculated from pentahydrate and decahydrate solubility
	The water solubility for disodium tetraborates as such cannot be determined because disodium tetraborates are converted into boric acid/borate upon dissolution in water. Water solubility studies at pH = 5, 7, 9 are not possible, because of the strong buffering capacity of boric acid/borate solutions and ion-pair formation in the presence of alkali-metal ions like Na, K. Temperature dependence of water solubility should be investigated
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	No reliable data available
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	Not relevant.
Partition coefficient (log P_{OW}) (state temperature)	pH_5: not investigated
	pH_7: not investigated
	pH_9: not investigated
	pH_7.5: -1.09 at 22°C in potassium/sodium phosphate buffer at a concentration of 0.0097 M boron (purity 99.0% w/w expressed as H_3BO_3).
	pH_unknown: -0.757 at 25 °C in water at concentration levels between 0.16 - 0.89 M boron (purity not indicated)
	pH_unknown: -0.74 in 2 M KCl at 25 °C pH_unknown: -0.56 in 3 M $NaClO_4$ at 25 °C pH_unknown: -0.55 in 3 M $NaClO_4$ at 35 °C
	The log P_{ow} for disodium tetraborates as such cannot be determined because disodium tetraborates are converted into boric acid/borate upon dissolution in water. The log

	P_{ow} given is the log P_{ow} for boric acid. The difference between log P_{ow} values obtained at different temperatures, different salinity, different concentration and different analysis, is only 0.5 log P_{ow} unit. No further tests are required.
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	The dissociation constant for disodium tetraborate anhydrous as such cannot be determined because disodium tetraborate anhydrous is converted into boric acid/borate upon dissolution in water: $Na_2B_4O_7 + 7\ H_2O = 2\ NaB(OH)_4 + 2\ B(OH)_3$. The dissociation constant found will be the dissociation constant for boric acid in the presence of sodium ions Boric acid is a Lewis acid (hydroxide ion acceptor) rather than a Brønsted acid (proton donator). For this purpose the formula for boric acid is best written as $B(OH)_3$. pKa = 9.0 at 25 °C for boric acid in dilute solutions only ($B \leq 0.025$ M). At higher boron concentrations, polynuclear complexes are formed and several dissociation/formation constants apply.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	No absorption maximum or minimum found in neutral, basic or acidic medium in the range 190-750 nm.
Flammability	Not required; a.s. known for flame retardant properties.
Explosive properties	Not explosive.

Physical and chemical properties for disodium tetraborate pentahydrate (Annex IIA, point III, unless otherwise indicated)

Melting point (state purity)	No melting point can be defined because of decomposition of the active substance (purity 101.7% (w/w) expressed as $Na_2B_4O_7.5H_2O$)
Boiling point (state purity)	No boiling point can be defined because of decomposition of the active substance (see melting point)
Temperature of decomposition	When disodium tetraborate pentahydrate is heated, it gradually loses water of crystallisation, forming disodium tetraborate anhydrous, $Na_2B_4O_7$. An endothermal peak is observed at 131 °C, probably due to the loss of water. Due to a phase transition an exothermal peak is observed at 524/527°C. The crystal form of $Na_2B_4O_7$ melts at 737°C
Appearance (state purity)	Solid white odourless powder (purity not stated)
Relative density (state purity)	1.860 at 22 °C (purity 101.7% (w/w) expressed as $Na_2B_4O_7.5H_2O$)
Surface tension	Not applicable
Vapour pressure (in Pa, state temperature)	Not applicable, because the melting point lies above 300 °C and at ambient temperature vapour pressure is expected to be less than 10^{-5} Pa.

Henry's law constant (Pa m^3 mol^{-1})	Not applicable, because the melting point lies above 300 °C and at ambient temperature vapour pressure is expected to be less than 10^{-}5 Pa.
Solubility in water (g/l or mg/l, state temperature)	pH_ 9.66: 40.06 g/L at 20.0°C (purity 101.7% (w/w) expressed as $Na_2B_4O_7.5H_2O$)
	The water solubility for disodium tetraborates as such cannot be determined because disodium tetraborates are converted into boric acid/borate upon dissolution in water. Water solubility studies at pH = 5, 7, 9 are not possible, because of the strong buffering capacity of boric acid/borate solutions and ion-pair formation in the presence of alkali-metal ions like Na, K. Temperature dependence of water solubility should be investigated
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	No reliable data available
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	Not relevant.
Partition coefficient (log P_{OW}) (state temperature)	pH_5: not investigated
	pH_7: not investigated
	pH_9: not investigated
	pH_7.5: -1.09 at 22°C in potassium/sodium phosphate buffer at a concentration of 0.0097 M boron (purity 99.0% w/w expressed as H_3BO_3).
	pH_unknown: -0.757 at 25 °C in water at concentration levels between 0.16 - 0.89 M boron (purity not indicated)
	pH_unknown: -0.74 in 2 M KCl at 25 °C pH_unknown: -0.56 in 3 M $NaClO_4$ at 25 °C pH_unknown: -0.55 in 3 M $NaClO_4$ at 35 °C
	The log P_{ow} for disodium tetraborates as such cannot be determined because disodium tetraborates are converted into boric acid/borate upon dissolution in water. The log P_{ow} given is the log P_{ow} for boric acid. The difference between log P_{ow} values obtained at different temperatures, different salinity, different concentration and different analysis, is only 0.5 log P_{ow} unit. No further tests are required.
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	The dissociation constant for disodium tetraborate pentahydrate as such cannot be determined because disodium tetraborate pentahydrate is converted into boric acid upon dissolution in water: $Na_2B_4O_7.5H_2O + 2\ H_2O = 2\ NaB(OH)_4 + 2\ B(OH)_3$. The dissociation constant found will be the dissociation constant for boric acid in the presence of sodium ions. Boric acid is a Lewis acid (hydroxide ion acceptor) rather than a Brønsted acid (proton donator). For this

	purpose the formula for boric acid is best written as $B(OH)_3$. pKa = 9.0 at 25 °C for boric acid in dilute solutions only ($B \leq 0.025$ M). At higher boron concentrations, polynuclear complexes are formed and several dissociation/formation constants apply.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	No absorption maximum or minimum found in neutral, basic or acidic medium in the range 190-750 nm, partly deduced from anhydrous spectrum.
Flammability	Not required; a.s. known for flame retardant properties.
Explosive properties	Not explosive.

Physical and chemical properties for disodium tetraborate decahydrate (Annex IIA, point III, unless otherwise indicated)

Melting point (state purity)	No melting point can be defined because of decomposition of the active substance (purity 99.0% (w/w) expressed as $Na_2B_4O_7.10H_2O$)
Boiling point (state purity)	No melting point can be defined because of decomposition of the active substance (see melting point)
Temperature of decomposition	When disodium tetraborate decahydrate is heated, it gradually loses water of crystallisation, first forming the pentahydrate $Na_2B_4O_7.5H_2O$, and on further heating forms disodium tetraborate anhydrous, $Na_2B_4O_7$. Two small endothermal peaks are observed at 47/48°C and 101/99°C, which are most likely due to the loss of crystal water. The crystal form of $Na_2B_4O_7$ melts at 737°C
Appearance (state purity)	Solid white odourless powder (purity not stated)
Relative density (state purity)	1.74 at 23 °C (purity 99.0% (w/w) expressed as $Na_2B_4O_7.10H_2O$)
Surface tension	Not applicable
Vapour pressure (in Pa, state temperature)	Not applicable, because the melting point lies above 300 °C and at ambient temperature vapour pressure is expected to be less than 10^{-5} Pa.
Henry's law constant (Pa m^3 mol^{-1})	Not applicable, because the melting point lies above 300 °C and at ambient temperature vapour pressure is expected to be less than $10^{-}5$ Pa.
Solubility in water (g/l or mg/l, state temperature)	pH_ 9.69: 49.74 g/L at 20.0°C (purity 99.0% (w/w) expressed as $Na_2B_4O_7.10H_2O$)
	The water solubility for disodium tetraborates as such cannot be determined because disodium tetraborates are converted into boric acid/borate upon dissolution in water. Water solubility studies at pH = 5, 7, 9 are not possible, because of the strong buffering capacity of boric

	acid/borate solutions and ion-pair formation in the presence of alkali-metal ions like Na, K. Temperature dependence of water solubility should be investigated
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	No reliable data available
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	Not relevant.
Partition coefficient (log P_{OW}) (state temperature)	pH_5: not investigated
	pH_7: not investigated
	pH_9: not investigated
	pH_7.5: -1.09 at 22°C in potassium/sodium phosphate buffer at a concentration of 0.0097 M boron (purity 99.0% w/w expressed as H_3BO_3).
	pH_unknown: -0.757 at 25 °C in water at concentration levels between 0.16 - 0.89 M boron (purity not indicated)
	pH_unknown: -0.74 in 2 M KCl at 25 °C pH_unknown: -0.56 in 3 M $NaClO_4$ at 25 °C pH_unknown: -0.55 in 3 M $NaClO_4$ at 35 °C
	The log P_{ow} for disodium tetraborates as such cannot be determined because disodium tetraborates are converted into boric acid/borate upon dissolution in water. The log P_{ow} given is the log P_{ow} for boric acid. The difference between log P_{ow} values obtained at different temperatures, different salinity, different concentration and different analysis, is only 0.5 log P_{ow} unit. No further tests are required.
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	The dissociation constant for disodium tetraborate decahydrate as such cannot be determined because disodium tetraborate decahydrate is converted into boric acid upon dissolution in water: $Na_2B_4O_7.10H_2O$ = $2NaB(OH)_4 + 2B(OH)_3 + 3H_2O$. The dissociation constant found will be the dissociation constant for boric acid in the presence of sodium ions. Boric acid is a Lewis acid (hydroxide ion acceptor) rather than a Brønsted acid (proton donator). For this purpose the formula for boric acid is best written as $B(OH)_3$. pKa = 9.0 at 25 °C for boric acid in dilute solutions only ($B \leq 0.025$ M). At higher boron concentrations, polynuclear complexes are formed and several dissociation/formation constants apply.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	No absorption maximum or minimum found in neutral, basic or acidic medium in the range 190-750 nm (partly deduced from anhydrous spectrum).

Flammability	Not required; a.s. known for flame retardant properties.
Explosive properties	Not explosive.

Classification and proposed labelling for disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate decahydrate

with regard to physical/chemical data	None
with regard to toxicological data	Toxic, R36-60-61
with regard to fate and behaviour data	None
with regard to ecotoxicological data	None

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	Method BS 5688 : Part 8 :1979 ISO 2216-1972 [ISO title: Crude sodium borates for industrial use- Determination of sodium oxide and boric oxide contents- Volumetric method]. The ISO method has been withdrawn on 27 May 2002 and is not supported by ISO anymore. Because the method is still in use in Australia and the ISO method was withdrawn for the sole reason that the method was not verified anymore every 5 years, the method is considered acceptable by the RMS.
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	Not required. No impurities > 1 g/kg and no (eco)toxicologically relevant impurities.

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	Total boron can be extracted from soil by hot acid extraction with HNO_3 and HCl under reflux or by microwave digestion with HNO_3 and HF, with addition of HCl and H_2O_2 when needed. Detection by ICP-AES (LOD ca. 4 µg B/L) or by photospectrometry after reaction with azomethine-H (LOD 0.01 – 1 mg B/L). LOQ depends on the extraction method
Air (principle of method and LOQ) (Annex IIA, point 4.2)	Not required.
Water (principle of method and LOQ) (Annex IIA, point 4.2)	Same methods as for soil
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	Although classified as Toxic, no method is required. The same method as for soil can be used.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not applicable
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not applicable

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, point 6.2)

Rate and extent of oral absorption:	100%
Rate and extent of dermal absorption:	0.5%
Distribution:	Absorbed boron rapidly distributes throughout the body water in humans and animals.
Potential for accumulation:	Low
Rate and extent of excretion:	Excreted almost exclusively in the urine. Half-life < 24 hours.
Toxicologically significant metabolite	Does not metabolise Most of the simple inorganic borates such as boric acid; boric oxide; disodium tetraborate and disodium octaborate tetrahydrate exist predominantly as un-dissociated boric acid in dilute aqueous solution at physiological pH, leading to the conclusion that the main species in the plasma of mammals is un-dissociated boric acid. Since other borates dissociate to form boric acid in aqueous solutions, they too can be considered to exist as un-dissociated boric acid under physiological conditions. For example disodium octaborate tetrahydrate a solid solution of boric acid and disodium tetraborate decahydrate

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	> 2500 mg/kg bw

Rat LD_{50} dermal	> 2000 mg/kg bw
Rat LC_{50} inhalation	> 2030 mg/m³ (highest attainable concentration)
Skin irritation	Non Irritant
Eye irritation	Irritant
Skin sensitization (test method used and result)	Non Sensitiser – Buehler and Human

Repeated dose toxicity (Annex IIA, point 6.3)

Species/ target / critical effect	Testis, blood
Lowest relevant oral NOAEL / LOAEL	17.5 mg boron /kg bw/day
Lowest relevant dermal NOAEL / LOAEL	No data
Lowest relevant inhalation NOAEL / LOAEL	No data

Genotoxicity (Annex IIA, point 6.6)	Negative

Carcinogenicity (Annex IIA, point 6.4)

Species/type of tumour	Negative
lowest dose with tumours	Not relevant

Reproductive toxicity (Annex IIA, point 6.8)

Species/ Reproduction target / critical effect	Rat; mouse and dog testis; Testicular atrophy
Lowest relevant reproductive NOAEL / LOAEL	17.5 mg boron/kg bw/day
Species/Developmental target / critical effect	Rat: reduction in mean fetal body weight/litter, increased incidence in short rib X111) Rabbit: increased incidence in major heart and/or great vessel malformations
Lowest relevant developmental NOAEL / LOAEL	9.6 mg boron/kg bw/day

Neurotoxicity / Delayed neurotoxicity (Annex IIIA, point VI.1)

Species/ target/critical effect	Not relevant
Lowest relevant developmental NOAEL / LOAEL.	Not relevant

Other toxicological studies (Annex IIIA, VI/XI)

	Not relevant

Medical data (Annex IIA, point 6.9)

	The human oral lethal dose is regularly quoted as 2-3 g boric acid for infants, 5-6 g boric acid for children and 15-30 g boric acid for adults. Acute effects of poisoning may include nausea, vomiting, gastric discomfort, skin flushing, excitation, convulsions, depression and vascular collapse. Multiple exposure to high levels of

	boron may result in dermatitis, alopecia, loss of appetite, nausea, vomiting, diarrhoea, and focal or generalised central nervous system irritation or convulsions. Workers exposed to borax dust at about 4 mg/m^3 reported eye irritation, dry mouth, nose or throat, sore throat, acute and chronic respiratory irritation and productive cough. In human populations exposed to high boron levels in drinking water or male workers of a borax mine no effects on reproduction were observed.

Summary (Annex IIA, point 6.10)	Value	Study	Safety factor
ADI (if residues in food or feed)	Not relevant		
AOEL (Operator/Worker Exposure) acute/semi-chronic and chronic	Rounded 0,1* mg B/kg bw/day	developmental study rat	100
Drinking water limit		EU Council Directive 98/83/EC. Quality of Water Intended for Human Consumption	
ARfD (acute reference dose)	not relevant		

* A rounded (systemic) AOEL value of 0.1 mg B/kg bw/day was used for disodium tetraborates based on the NOAEL for embryotoxic/teratogenic effects of 9.6 mg B/kg bw/day and a standard assessment factor of 100 even though an AOEL value of 0.06 mg B/kg bw/day (based on a NOAEL of 17.5 mg B/kg bw/day in a 2-year study in the rat and an assessment factor of 300 due to serious effects) and an AOEL value of 0.07 mg B/kg bw/day (based on a NOAEL of 21.8 mg B/kg bw/day in a teratogenicity study in the rabbit and an assessment factor of 300 due to serious effects) could be derived from the critical effects.

Acceptable exposure scenarios (including method of calculation)

Professional users	Adverse health effects for the unprotected professional user due to the combined dermal and respiratory exposure of boric acid cannot be excluded. By using PPE sufficient reduction of the exposure can be achieved.
Non-professional users	Adverse health effects for the unprotected non-professional user due to the combined dermal and respiratory exposure of boric acid, as a result of spraying or brushing can be excluded. However, biocidal products containing more then 4.5% disodium tertaborate anhydrous and classified with R60-61 shall not be authorised for marketing to, or use by the general public. Biocidal products containing more then 6.5% disodium tertaborate pentahydrate and classified with R60-61 shall not be authorised for marketing to, or use by the general public. Biocidal products containing more then 8.5% disodium tertaborate anhydrous and classified with R60-61 shall not be authorised for marketing to, or use by the general public
Indirect exposure as a result of use	No adverse health effects for the non-professional user and the professional user due to indirect exposure are

	expected. For a child playing on a playground structure outdoors a health risk as a consequence of exposure to borates can be excluded.

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water (Annex IIA, point 7.6, IIIA, point XII.2.1, 2.2)

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	hydrolytically stable
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	photolytically stable
Quantum yield of direct phototransformation in water at $\lambda > 290$ nm (point VII.7.6.2.2)	not applicable
Readily biodegradable (yes/no)	No
Biodegradation in seawater	not applicable
Non-extractable residues	Not applicable
Distribution in water / sediment systems (active substance)	no information supplied
Distribution in water / sediment systems (metabolites)	not applicable

Route and rate of degradation in soil (Annex IIIA, point VII.4, XII.1.1, XII.1.4; Annex VI, para. 85)

Mineralization (aerobic)	not applicable
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): not applicable
	DT_{90lab} (20°C, aerobic): not applicable
	DT_{50lab} (10°C, aerobic): not applicable
	DT_{50lab} (20°C, anaerobic): not applicable
	degradation in the saturated zone: not applicable
Field studies (state location, range or median with number of measurements)	DT_{50f}: not applicable
	DT_{90f}: not applicable
Anaerobic degradation	not applicable
Soil photolysis	not applicable
Non-extractable residues	not applicable
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	not applicable
Soil accumulation and plateau concentration	not available

Adsorption/desorption (Annex IIA, point XII.7.7; Annex IIIA, point XII.1.2)

Ka , Kd	Average K_F 2.6 L/kg (range 0.4 – 8.41 L/kg; n = 9); average 1/n 0.83 (range 0.726 – 0.955)
Ka_{oc} , Kd_{oc}	no clear relationship with OC
pH dependence (yes / no) (if yes type of dependence)	no

Fate and behaviour in air (Annex IIIA, point VII.3, VII.5)

Direct photolysis in air	does not photolyse
Quantum yield of direct photolysis	not applicable
Photo-oxidative degradation in air	not applicable
Volatilization	Negligible – vapour pressure 9.9 x 10^{-6} Pa at 25°C

Monitoring data, if available (Annex VI, para. 44)

Soil (indicate location and type of study)	Range 45-124 mg/kg worldwide
Surface water (indicate location and type of study)	Range < 0.001 – 0.632 mg B/L in surface water (review of monitoring values for 15 EU countries)
Ground water (indicate location and type of study)	not available
Air (indicate location and type of study)	Estimated as 20 ng/m^3 (monitoring values near coastlines)

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)
(Annex IIA, point 8.2, Annex IIIA, point 10.2)

Species	Time-scale	Endpoint	Toxicity
Fish			
Catostomus latipinnis	acute (96 h)	LC50	125 mg B/L
Brachydanio rerio	chronic (34 d)	NOEC	1.8 mg B/L
Invertebrates			
Daphnia magna	acute (48 h)	L(E)C50	141 mg B/L
Daphnia magna	chronic (21 d)	NOEC	10 mg B/L
Algae			
Selenastrum capricornutum	chronic (74.5 h)	NOEC (growth inhibition)	17.5 mg B/L
Microorganisms			
Activated sludge	chronic (3 h)	NOEC (respiration inhibition)	17.5 mg B/L
An assessment factor of 10 was applied to the lowest chronic NOEC of 1.8 mg B/l. Resulting in a $PNEC_{add, aquatic}$ of 0.18 mg B/l.			

Effects on earthworms or other soil non-target organisms (most sensitive species for each group)

Acute toxicity for earthworms (Annex IIIA, point XIII.3.2)	14-days LC_{50} *Lumbricus terrestris*: 473 mg B/kg dwt (geomean of 501 and 447)
Reproductive toxicity for earthworms (Annex IIIA, point XIII.3.2)	63-days NOEC *Eisenia andrei*: 54 mg B/kg dwt soil (geomean of 39, 79, 52, 52)
Reproductive toxicity for springtails	28-days NOEC Juvenile reproduction *Folsomia candida:* 14 mg B/kg dwt soil (geomean of 14 and 14)
Toxicity to plants	120-days NOEC root/shoot ratio *Hordeum vulgare:* 2 mg B/kg dwt soil
An assessment factor of 5 was applied to the lowest chronic NOEC of 2 mg B/kg dwt. Resulting in a PNECadd,soil of 0.4 mg B/kg dwt or 0.35 mg B/kg wwt.	

Effects on soil micro-organisms (Annex IIA, point 7.4)

Nitrogen mineralization	20-days EC_{10}: 54 mg B/kg dwt soil
Carbon mineralization	no data available
Effects on terrestrial vertebrates	
Acute toxicity to mammals (Annex IIIA, point XIII.3.3)	Oral LD_{50} Rat: 3450 mg/kg bw
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	LD_{50} C*olinus virginianus*: > 527 mg B/kg bw
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	5-days LC50 *Colinus virginianus*: > 983 mg B/kg fd; > 571 mg B/kg bw.d *Anas platyrhynchos*: > 2100 mg B/kg fd
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	no data available

Effects on honeybees (Annex IIIA, point XIII.3.1)

Acute oral toxicity	no data available
Acute contact toxicity	no data available

Effects on other beneficial arthropods (Annex IIIA, point XIII.3.1)

Acute oral toxicity	no data available
Acute contact toxicity	no data available
Acute toxicity to	no data available

Bioconcentration (Annex IIA, point 7.5)

Bioconcentration factor (BCF)	BAF < 10 L/kg (fish) BAF < 30 L/kg (plankton and invertebrates)
Depuration time (DT_{50}) (DT_{90})	virtually all boron was eliminated within 24 days
Level of metabolites (%) in organisms accounting for > 10% of residues	no data available

Appendix II: List of Intended Uses

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount, assuming a wood density of 500 kg/m^3 (pine wood)			
				Type	Conc of as	Method kind	No	Interval between applications	kg/m^3, BAE in wood	% (w/w), BAE in wood	% (w/v) BAE in treatment solution	kg/m^2, BAE on wood
Wood preservation (PT08) Preventive, UC 1,2,3	All Member States	model product containing disodium tetraborates (b)	decay fungi; wood boring insects	powder; stand alone product	> 99.0%	industrial; vacuum pressure; closed mixing process; ambient temp	1	na	2.0	0.4	6-12 (a)	na
			Termites	powder; stand alone product	> 99.0%	industrial; vacuum pressure; closed mixing process; ambient temp	1	na	8.5	1.7	6-12 (a)	na
Wood preservation (PT08) Preventive, UC 1,2,3	All Member States	model product containing disodium tetraborates (b)	decay fungi; wood boring insects	powder; stand alone product	> 99.0%	industrial; double vacuum pressure; closed mixing process; ambient temp	1	na	2.0	0.4	6-12 (a)	na
			Termites	powder; stand alone product	> 99.0%	industrial; double vacuum pressure; closed mixing process; ambient temp	1	na	8.5	1.7	6-12 (a)	na
Wood preservation (PT08) Preventive, UC 1,2,3	All Member States	model product containing disodium tetraborates (b)	decay fungi; wood boring insects	powder; stand alone product	> 99.0%	industrial; automated dipping; closed mixing process temp 40-60 °C	1	na	n.a.	n.a.	12-35 (a)	0.05
Wood preservation (PT08) Preventive, UC 1,2,3	All Member States	model product containing disodium tetraborates (b)	decay fungi; wood boring insects	powder; stand alone product	> 99.0%	industrial; deluge; closed mixing process temp 40-60 °C	1	na	n.a.	n.a.	12-35 (a)	0.05
Wood preservation (PT08) Preventive, UC 1,2,3	All Member States	model product containing disodium tetraborates (b)	decay fungi; wood boring insects	powder; stand alone product	> 99.0%	industrial; automated spraying; closed mixing process temp 40-60 °C	1	na			12-35 (a)	0.05
Wood preservation (PT08) Remedial, UC 4a	All Member States	model product containing disodium tetraborates (b)	decay fungi; wood boring insects	powder; stand alone product	> 99.0%	professional; in-situ injection; on-site mixing; ambient temp	1-10	1 hr to 1 yr	2.0	0.4	6-12 (a)	na

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount, assuming a wood density of 500 kg/m^3 (pine wood)			
				Type	Conc of as	Method kind	No	Interval between applications	kg/m^3, BAE in wood	% (w/w), BAE in wood	% (w/v) BAE in treatment solution	kg/m^2, BAE on wood
Wood preservation (PT08) Remedial, UC 4a	All Member States	model product containing disodium tetraborates (b)	decay fungi; wood boring insects	powder; stand alone product	> 99.0%	professional; in-situ brushing; on-site mixing; ambient temp	1-10	1 hr to 1 yr	n.a.	na	6-12 (a)	0.05
Wood preservation (PT08) Remedial, UC 4a	All Member States	model product containing disodium tetraborates (b)	decay fungi; wood boring insects	powder; stand alone product	> 99.0%	professional; in-situ spraying; on-site mixing; ambient temp	1-10	1 hr to 1 yr	n.a.	na	6-12 (a)	0.05
Wood preservation (PT08) Remedial, UC 4a	All Member States	model product containing disodium tetraborates (b)	decay fungi; wood boring insects	concentrated dilution; stand alone product	63	amateur; in-situ brushing; ambient temp	1	na	na	na	6-12 (a)	0.05
Wood preservation (PT08) Remedial, UC 4a	All Member States	model product containing disodium tetraborates (b)	decay fungi; wood boring insects	Concentrated dilution; stand alone product	63	amateur; in-situ spraying; ambient temp	1	na	n.a.	n.a.	6-12 (a)	0.05

na = not applicable

BAE = boric acid equivalents. For boric acid the conversion factor from boric acid weight units (e.g. gram) to boric acid equivalent weight units (e.g. gram) is 1. The conversion factor from BAE to boron equivalent is 0.175.

UC1•	Use Class 1 timber under cover including indoor joinery (preventive)
UC2	Use Class 2 timber under cover including indoor roofing timbers – risk of wetting (preventive)
UC3	Use Class 3 exterior timbers out of ground contact, including joinery protected with a surface coating (preventive)
UC4a	Use Class 4a remedial application to timbers in service in ground contact (curative).
(a)	Solubility for boric acid is about 50 g/L, or 5% (w/v) BAE; therefore concentrations of 6-35% (w/v) for treatment solutions are not possible

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed" column of the table below. For studies marked Yes(i) data protection is claimed under Article 12.1(c) (i), for studies marked Yes(ii) data protection is claimed under Article 12.1(c) (ii). These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

BEU = Borax Europe Limited

Reference list of studies on the active substance

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A2.1/01	Merck Index	1996	Merck Index on CD-rom, version 12.1, 1996	No	
A2.5/01	CRC	1999	CRC Handbook of Chemistry and Physics, electronic version 1999. Non-GLP Published	No	
A2.10/01	Smith, R.A, Ascherl, F.M	1999	Issues concerning the measurement of borate in occupational environments. Am. Ind. Hyg. Assoc. J., 60, No. 5, p.651-658. (September - October 1999)	No	
A3.1.1/01 (anhydrous, pentahydrate, decahydrate)	Kirk-Othmer Encyclopedia	1992	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 4th Edition, Volume 4, pp 368-386. Non-GLP Published	No	
A3.1.1/02 (anhydrous, pentahydrate)	Cordia JA, Bal EA, Mak WA and Wils ERJ	2003	Determination of some physico-chemical properties of Neobor, Rijswijk, The Netherlands: TNO Prins Maurits Laboratory, report PML 2002-C41rr, August 2003 Borax Europe Ltd GLP, provisional: unauthorised version Unpublished	Yes	BEU
A3.1.1/03 (decahydrate)	Cordia JA, Bal EA, Mak WA and Wils ERJ	2003	Determination of some physico-chemical properties of Borax Decahydrate, Rijswijk, The Netherlands, TNO Prins Maurits Laboratory, report PML 2002-C43rr, August 2003, Borax Europe Ltd GLP Unpublished	Yes	BEU
A3.1.2/01 (anhydrous)	CRC	1999	CRC Handbook of Chemistry and Physics, electronic version 1999. Non-GLP Published	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.1.3/01 (anhydrous)	Spruit WET, Van Baar BLM and Wils ERJ	2005	Determination of some physical chemical properties of sodium tetraborate anhydrous. Rijswijk, The Netherlands, TNO Defence Security and Safety. Report TNO-DV2 2005-PU003. Borax Europe Ltd. GLP Unpublished	Yes	BEU
A3.1.3/02 (pentahydrate)	Cordia JA, Bal EA, Mak WA and Wils ERJ	2003	Determination of some physico-chemical properties of Neobor, Rijswijk, The Netherlands: TNO Prins Maurits Laboratory, report PML 2002-C41rr, August 2003 Borax Europe Ltd GLP, provisional: unauthorised version Unpublished	Yes	BEU
A3.1.3/03 (decahydrate)	Kirk-Othmer Encyclopedia	1992	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 4th Edition, Volume 4, pp 368-386. Non-GLP Published	No	
A3.1.3/04 (decahydrate)	Cordia JA, Bal EA, Mak WA and Wils ERJ	2003	Determination of some physico-chemical properties of Borax Decahydrate, Rijswijk, The Netherlands, TNO Prins Maurits Laboratory, report PML 2002-C43rr, August 2003, Borax Europe Ltd GLP Unpublished	Yes	BEU
A3.2/01 (anhydrous, pentahydrate)	Tremain SP	1998	Boric acid: determination of vapour pressure. Derby, UK: Safepharm Laboratories Ltd, SPL project number 1231/002. Borax Europe Ltd. GLP Unpublished	Yes	BEU
A3.2/02 (anhydrous, pentahydrate)	Howarth R, Tremain SP, Bartlett AJ	1995	Disodium octaborate tetrahydrate determination of vapour pressure. Derby, UK: SafePharm Laboratories Ltd, Project number 801/010 Borax Consolidated Ltd. GLP Unpublished	Yes	BEU
A3.2/03 (decahydrate)	Kirk-Othmer Encyclopedia	1992	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 4th Edition, Volume 4, pp 368-386. Non-GLP Published	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.4/01 (anhydrous)	Spruit WET, Van Baar BLM and Wils ERJ	2005	Determination of some physical chemical properties of sodium tetraborate anhydrous. Rijswijk, The Netherlands, TNO Defence Security and Safety. Report TNO-DV2 2005-PU003. Borax Europe Ltd. GLP Unpublished	Yes	BEU
A3.4/02 (pentahydrate)	Cordia JA, Bal EA, Mak WA and Wils ERJ	2003	Determination of some physico-chemical properties of Neobor, Rijswijk, The Netherlands: TNO Prins Maurits Laboratory, report PML 2002-C41rr, August 2003 Borax Europe Ltd GLP, provisional: unauthorised version Unpublished	Yes	BEU
A3.4/03 (pentahydrate)	Spruit WET	2005	Determination of some physical chemical properties of sodium tetraborate pentahydrate. Rijswijk, The Netherlands: TNO Defence, Security and Safety. Report TNO-DV2 2005-PU005. Borax Europe Lts GLP Unpublished	Yes	BEU
A3.4/04 (decahydrate)	Cordia JA, Bal EA, Mak WA and Wils ERJ	2003	Determination of some physico-chemical properties of Borax Decahydrate, Rijswijk, The Netherlands, TNO Prins Maurits Laboratory, report PML 2002-C43rr, August 2003, Borax Europe Ltd GLP Unpublished	Yes	BEU
A3.4/05 (decahydrate)	Spruit WET	2005	Determination of some physical chemical properties of sodium tetraborate decahydrate. Rijswijk, The Netherlands: TNO Defence, Security and Safety, report TNO-DV2 2005-PU006. Borax Europe Ltd. GLP Unpublished.	Yes	BEU
A3.5/01 (anhydrous, pentahydrate, decahydrate)	Mellor's Comprehensive	1980	Supplement to Mellor's comprehensive treatise on inorganic and theoretical chemistry, Volume V, Boron, Part A: Boron-Oxygen Compounds, Longman London and New York, ISBN 0-582-46277-0, pp 170-213, pp 224-320, pp 343-344, pp 356-387, and pp 409-500. Non-GLP Published	No	

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A3.5/02 (anhydrous, pentahydrate, decahydrate)	Kirk-Othmer Encyclopedia	1992	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 4th Edition, Volume 4, pp 368-386. Non-GLP Published	No	
A3.5/03 (pentahydrate)	Cordia JA, Bal EA, Mak WA and Wils ERJ	2003	Determination of some physico-chemical properties of Neobor, Rijswijk, The Netherlands: TNO Prins Maurits Laboratory, report PML 2002-C41rr, August 2003 Borax Europe Ltd GLP, provisional: unauthorised version Unpublished	Yes	BEU
A3.5/04 (decahydrate)	Cordia JA, Bal EA, Mak WA and Wils ERJ	2003	Determination of some physico-chemical properties of Borax Decahydrate, Rijswijk, The Netherlands, TNO Prins Maurits Laboratory, report PML 2002-C43rr, August 2003, Borax Europe Ltd GLP Unpublished	Yes	BEU
A3.6/01 (anhydrous, pentahydrate, decahydrate)	Bell RP, Edwards JO and Jones RB	1967	The structure and acidity of boric acid and their relation to reaction mechanisms. In: The chemistry of boron and its compounds. pp 209-221 Non GLP Published	No	
A3.6/02 (anhydrous, pentahydrate, decahydrate)	Kankaanpera A and Salomaa P.	1969	The structure of boric acid in aqueous solution. Acta Chem. Scand. 23, No. 2, 712-713 Non-GLP Published	No	
A3.6/03 (anhydrous, pentahydrate, decahydrate)	Jenkins HO	1945	Transactions of the Faraday Society 41, 138-140 Non-GLP Published	No	
A3.6/04 (anhydrous, pentahydrate, decahydrate)	WHO.	1998	Guidelines for drinking water quality. 2nd Edition Addendum to Vol 2 Boron, page 15, World Health Organisation, Geneva. Non-GLP Published	No	
A3.6/05 (anhydrous, pentahydrate, decahydrate)	Hahn FL and Klockmann R	1930	Die höheren Dissoziationsstufen der Phosphorsaüre und der Borsaüre Z physik. Chem., 151, 80-86. Non-GLP Published	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.6/06 (anhydrous, pentahydrate, decahydrate)	Ingri N	1963	Equilibrium studies of polyanions containing B^{III}, Si^{IV}, Ge^{IV}, and V^{V}. Sven. Kem. Tidskr. 75(4):199-230. Non-GLP Published	No	
A3.6/07 (anhydrous, pentahydrate, decahydrate)	Maeda M	1979	Raman spectra of polyborate ions in aqeous solution. J Inorg. Nucl. Chem. vol 41: 1217-1220 Non-GLP Published	No	
A3.6/08 (anhydrous, pentahydrate, decahydrate)	Farmer J	1982	Structural chemistry in the borate industry, Chem and Ind Non-GLP Published	No	
A3.6/09 (anhydrous, pentahydrate, decahydrate)	Kirk-Othmer Encyclopedia	1992	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 4th Edition, Volume 4, pp 368-386. Non-GLP Published	No	
A3.6/10 (anhydrous, pentahydrate, decahydrate)	Holleman AF and Wiberg E and Wiberg N	1995	Lehrbuch der anorganischen Chemie. 101st ed. De Gruyter, Berlin	No	
A3.6/11 (anhydrous, pentahydrate, decahydrate)	De Vette HQM, Otto C, Schoonmade MA	2001	Hydrolysis as a function of pH and identification of breakdown products. A study on the indentification and comparison of the dissociation products of Polybor tech, Borax Manufacturing grade and Boric acid manufacturing grade in aqeous solution using Raman spectroscopy. TNO report no v99-1153 (TX-2001-001)	Yes	BEU
A3.7/01 (anhydrous)	Kirk-Othmer Encyclopedia	1992	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 4th Edition, Volume 4, pp 368-386. Non-GLP Published	No	
A3.7/02 (pentahydrate)	Borax Europe Ltd	no date	Product Profile Neobor, Borax Europe Ltd, PP2-JH1-3-EU. Non-GLP Published	Yes	BEU
A3.7/03 (decahydrate)	Borax Europe Ltd	1999	Product Profile Borax Decahydrate, Borax Europe , PP1-JJ9-11-WW. Non-GLP Published	Yes	BEU

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A3.9/01 (anhydrous, pentahydrate, decahydrate)	Barres M	1967	Contribution to the study of the isopolycondensation of alcaline borates by electrometry and partition Rev. Chim. Miner., 4, 803-838; Non-GLP Published	No	
A3.9/02 (anhydrous, pentahydrate, decahydrate)	Cordia JA, Bal EA, Mak WA, Wils ERJ.	2003	Determination of some physico-chemical properties of Optibor EP. Rijswijk, The Netherlands: TNO Prins Maurits Laboratory. report PML 2002-C42rr, August 2003 Borax Europe Ltd. GLP, provisional: unauthorised version Unpublished	Yes	BEU
A3.9/03 (decahydrate)	Cordia JA, Bal EA, Mak WA and Wils ERJ	2003	Determination of some physico-chemical properties of Borax Decahydrate, Rijswijk, The Netherlands, TNO Prins Maurits Laboratory, report PML 2002-C43rr, August 2003, Borax Europe Ltd GLP Unpublished	Yes	BEU
A3.10/01 (anhydrous, pentahydrate)	Kirk-Othmer Encyclopedia	1992	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 4th Edition, Volume 4, pp 368-386. Not GLP Published	No	
A3.13/01 (anhydrous, pentahydrate, decahydrate)	Wurster ED	1963	Surface tension of aqueous 5-mol borax solutions. Ansheim, California, USA: US Borax Research Corporation, Technical Service Report No. 29A-1. Non-GLP Unpublished	Yes	BEU
A3.15/01 (anhydrous, pentahydrate, decahydrate)	Mak WA	2004	Statement 014.16017/01.35. Rijswijk, The Netherlands: TNO Prins Maurits Laboratory Non-GLP Unpublished	Yes	BEU
A3.16/01 (anhydrous, pentahydrate, decahydrate)	Mak WA	2004	Statement 014.16017/01.35. Rijswijk, The Netherlands: TNO Prins Maurits Laboratory Non-GLP Unpublished	Yes	BEU

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A 4.1/01	BSI	1979	BS 5688: Part 8: 1979, ISO 2216-1972 British standard methods of test for boric acid, boric oxide, disodium tetraborates, sodium perborates and crude sodium borates for industrial use. Part 8. Determination of sodium oxide and boric oxide contents of crude sodium borates (ISO title: Crude Sodium Borates For Industrial Use-Determination Of Sodium Oxide And Boric Oxide Contents- Volumetric Method) Non-GLP Published	No	BSI/ISO
A5/01	Ingri N	1963	Equilibrium studies of polyanions containing B^{III}, Si^{IV}, Ge^{IV}, and V^{V}. Sven. Kem. Tidskr. 75(4):199-230. Non-GLP Published	No	
A5/02	Kirk-Othmer Encyclopedia	1992	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 4th Edition, Volume 4, pp 368-386. Non-GLP Published	No	
A5/03	De Vette HQM, Otto C, Schoonmade MA	2001	Hydrolysis as a function of pH and identification of breakdown products. A study on the indentification and comparison of the dissociation products of Polybor tech, Borax Manufacturing grade and Boric acid manufacturing grade in aqeous solution using Raman spectroscopy. TNO report no v99-1153 (TX-2001-001)	Yes	BEU
A5/04	Maeda M	1979	Raman spectra of polyborate ions in aqeous solution. J Inorg. Nucl. Chem. vol 41: 1217-1220 Non-GLP Published	No	
A5/05	Lloyd JD	1993	The mechanisms of action of boron containing preservatives. Thesis submitted for degree of Doctor of Philosophy of the University of London and the Diploma of Membership of Imperial College (page 45 and 47 Tables 4 and 5) Non-GLP Published	No	
A5.3/01	Harrow KM	1950	Toxicity of water-soluble wood-preservatives to wood-destroying fungi. NZ Journal Sci. & Tech. Vol B 31, (5):14-19. Non-GLP Published	No	

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A5.3/02	Baechler RH and Roth HG	1956	Laboratory leaching and decay tests on pine and oak blocks treated with several preservative salts. Amer. Wood Preserver's Assoc. Proc. Annu. Meet., 52:24-34 Non-GLP Published	No	
A5.3/03	Carr DR	1957	Toxicities of some water-borne wood preservatives to wood destroying fungi. New Zealand Forest Service, FRI report, VF 841.12:844.2 (931) CAR, 32 pages. Non-GLP Unpublished	No	
A5.3/04	Becker G, Hof T, Jacquiot C, Lohwag K, Rennerfelt E and Walchli O	1966	Vergleichsversuche zur Laboratoriumsprüfung der pilzwidrigen Wirksamkeit von Holzschutzmitteln. Holz Roh-Werkst. 24 (2):53-58. Non-GLP Published	No	
A5.3/05	Gallagher LU	1968	Test of combined toxicity of Timbor and decay resistance of redwood heartwood. UK: Ministry of Technology, Forest Products Reseach Laboratory, Experiment 504 Non-GLP Unpublished	No	
A5.3/06	Smith RS	1969	Wood preservative toxicity evaluation using wood weight loss and fungal respiration methods. Wood Science 2(1):44-53 Non-GLP Published	No	
A5.3/07	Bechgaard C, Borup L, Henningsson B and Jermer J	1979	Remedial treatment of creosoted railway sleepers of redwood by selective application of boric acid. Stockholm, Sweden: Swedish Wood Preservation Institute, report no 135E, ISSN 0346-7090. Non-GLP Published	No	
A5.3/08	Doi S, Mori M and Mineki Y	1994	Preservative efficacy of boric acid triethanol amine solution against wood decay fungi. Stockholm, Sweden: The International Research Group on Wood Preservation, document IRG/WP 94-30050 Paper prepared for the 25th Annual Meeting, Bali, Indonesia, May-June, 1994 Non-GLP Published	No	

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A5.3/09	Cookson LJ and Pham K	1996	Relative tolerance of twenty basidiomycetes to boric acid. Mat und Org 29 (3) 187-196. Non-GLP Published	No	CSIRO
A5.3/10	Cummins JE and Wilson HB	1936	The preservation of timber against the attacks of powder post borer (*Lyctus brunneus* Stephens) by impregnation with various chemicals. J. Counc. Sci. Ind. Res., 9(1):37-56. Non-GLP Published	No	
A5.3/11	Cummins JE	1939	The preservation of timber against the attacks of powder post borer (*Lyctus brunneus* Stephens) by impregnation with boric acid. J. Counc. Sci. Ind. Res., 12(1):30-49. Non-GLP Published	No	
A5.3/12	Spiller D	1948	Toxicity of boric acid to the common house borer, *Anobium punctatum*. Wellington, New Zealand: Department of Scientific and Industrial Research, Extract from the NZ Journal Sci. & Tech. Vol B 30 (20):22-30. Non-GLP Published	No	
A5.3/13	Taylor JM	1967	Toxicity of boron compounds to the common furniture beetle and house longhorn beetles. International Pest Control 9(1):14-17. Non-GLP Published	No	
A5.3/14	Mauldin JK and Kard BM	1996	Disodium octaborate tetrahydrate treatments to slash pine for protection against Formosan subterranean termite and eastern subterranean termite. J. of Economic Entomology 89:682-688. Non-GLP Published	No	
A5.3/15	Findlay WPK	1959	Boron compounds for the preservation of timber against fungi and insects. 6th Wood Protection Congress of the German Society for Wood Research July, 1959 Reprinted in Pest Technology 2(6):124-127 Non-GLP Published	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A5.3/16	Becker G	1959	Beitrag zur Kenntnis der Wirksamkeit von Borverbindungen als Holzschutzmittel gegen Insekten und Pilze. Holz als Roh und Werkstoff 17(12):484-489. Non-GLP Published	No	
A5.3/17	Bravery AF and Carey JK	1983	A review of the data on the toxicity of boric acid to fungi and insects attacking wood. Building Research Advisory Service, Job no. P820648 Non-GLP Published	No	
A5.3/18	Borax Europe Ltd	2005	Explanatory note on efficacy assessment, application rates, environmental exposure assessment, boric acid. Borax Europe Ltd Non-GLP Unpublished	Yes	BEU
A5.4.1/01	Lloyd JD	1998	Borates and their biological applications. Stockholm, Sweden: The International Research Group on Wood Preservation. Doc no. IRG/WP98-30178. Paper prepared for the 29th annual meeting , Maastricht, The Netherlands, June 1998 Non-GLP Published.	No	
A5.4.1/02	Lloyd JD and Dickinson DJ	1991	Comparison of the inhibitory effects of borate, germanate, tellurate, arsenite and arsenate on 6-phosphogluconate dehydrogenase. Stockholm, Sweden: The International Research Group on Wood Preservation. Doc no. IRG/WP1508 Paper prepared for the 22nd annual meeting , Kyoto, Japan, May 1991. No GLP Published	No	
A5.4.1/03	Lloyd JD, Dickinson DJ and Murphy RJ	1990	The probable mechanisms of action of boric acid and borates as wood preservatives. Stockholm, Sweden: The International Research Group on Wood Preservation. Doc no. IRG/WP1450. Paper prepared for the 21st annual meeting , Rotorua, New Zealand, May 1990 Non GLP Published	No	

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A5.4.1/04	Lloyd JD, Dickinson DJ and Murphy RJ	1991	The effect of sorbitol on the decay of boric acid treated Scots pine. Stockholm, Sweden: The International Research Group on Wood Preservation. Doc no. IRG/WP1509. Paper prepared for the 22nd annual meeting , Kyoto, Japan, May 1991 Non-GLP Published	No	
A6.1.5/02	Bruze M, E. Hradil, I-L. Eriksohn, B. Gruvberger and L.Widstrom, Occupational	1995	Occupational allergic contact dermatitis from alkanolamineborates in metalworking fluids, Contact Dermatitis 32, 24 -27 (1995). No GLP Unpublished	No	
A6.2/02	Wester RC, Hui X, Hartway T, Maibach HI, Bell K, Schell MJ, Northington DJ, Strong P and Culver, BD	1998	In vivo percutaneous absorption of boric acid, Borax and disodium octaborate tetrahydrate in humans compared to in vitro absorption in human skin from infinite to finite doses. Toxicol Sciences 45 42-51 (1998) No GLP Unpublished	No	
A6.4.1/01	Weir RJ.	1996	Two-Year Dietary Feeding -- Dogs. Borax (Sodium Tetraborate Decahydrate). Final Report. Hazleton Laboratories, Inc. Report TX-66-20. July 8, 1966. (1967) No GLP Published	Yes	BEU
A6.4.1/02	Weir RJ	1997	38-Week Dietary Feeding – Dogs. Borax (Sodium Tetraborate Decahydrate). Final Report. Hazleton Laboratories. Report TX-67-4. February 28, 1967. No GLP Published	Yes	BEU
A6.4.1/03	Weir RJ and Fisher RS.	1972	Toxicological studies on borax and boric acid. Toxicol Appl Pharmacol. 23(3):351-64 No GLP Published	No	
A6.4.1/04	IPCS	1998	Environmental Health Criteria 204. Boron. P. 86. No GLP Published	No	
A6.4.1/05	Ku, W.W., R. E. Chapin, R. N. Wine, and B. C. Gladen,	1993	Testicular toxicity of boric acid (BA): Relationship of dose to lesion development and recovery in the F344 rat. Reprod. Toxicol. 7, 305-319 (1993). No GLP Published	Yes	BEU

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.4/06	Paynter, OE	1966	90 Day Dietary Feeding -- Dogs. Borax. Hazleton Laboratories. Report TX-63-1. January 17, 1963. No GLP Unpublished.	Yes	BEU
A6.2-10/01	Farmer J	1982	Structural chemistry in the borate industry, Chem and Ind Non-GLP Published	No	
A6.2-10/02	Ingri, N	1963	Equilibrium studies of polyanions containing BIII, SiIV, GeIV, and VV. Sven. Kem. Tidskr. 75(4):199-230. Non-GLP Published	No	
A6.2-10/03	Kirk-Othmer Encyclopedia	1992	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 4th Edition, Volume 4, pp 368-386. Non-GLP Published	No	
A6.2-10/04	Holleman AF and Wiberg E and Wiberg N	1995	Lehrbuch der anorganischen Chemie. 101st ed. De Gruyter, Berlin	No	
A6.2-10/05	De Vette HQM, Otto C, Schoonmade MA	2001	Hydrolysis as a function of pH and identification of breakdown products. A study on the indentification and comparison of the dissociation products of Polybor tech, Borax Manufacturing grade and Boric acid manufacturing grade in aqeous solution using Raman spectroscopy. TNO report no v99-1153 (TX-2001-001)	Yes	BEU
A6.2-10/06	Maeda, M	1979	Raman spectra of polyborate ions in aqeous solution. J Inorg. Nucl. Chem. vol 41: 1217-1220 Non-GLP Published	No	
A6.2-10/07	Rickards, H and Arian, Z	2004	, Rate of Dissolution Study of Borax's Products, Borax Europe Limted Internal Technical Report. TR-2004-01 No GLP Unpublished	Yes	BEU
A6.14/01	Cain WS, Jalowayski AA, Kleinman M, Lee NS, Lee BR, Ahn B-H, Magruder K, Schmid R and Culver BD	2002	Sensory perception of mineral dusts at occupationally relevant concentrations. USA: University of California, SAN: Laboratory Department of Surgery (Otolaryngology). Interim Draft report, January 2002 US Borax Inc. Non-GLP Unpublished.	Yes	BEU

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A6.14/02	Cain WS, Jalowayski AA, Kleinman M, Lee NS, Lee BR, Ahn B-H, Magruder K, Schmid R, Hillen BK, Warren CB and Culver BD	2004	Sensory and associated reactions to mineral dusts: sodium borate, calcium oxide, and calcium sulfate. J. Occupational Environm. Hygiene, 1:1-14, in press Non-GLP Published.	No	
A7.1.1.1.1/01	De Vette HQM, Otto C, Schoonmade MA	2001	Hydrolysis as a function of pH and identification of breakdown products. A study on the indentification and comparison of the dissociation products of Polybor tech, Borax Manufacturing grade and Boric acid manufacturing grade in aqeous solution using Raman spectroscopy. TNO report no v99-1153 (TX-2001-001)	Yes	BEU
A7.1.1.1.1/02	Farmer J	1982	Structural chemistry in the borate industry, Chem and Ind Non-GLP Published	No	
A7.1.1.1.1/03	Holleman AF and Wiberg E and Wiberg N	1995	Lehrbuch der anorganischen Chemie. 101st ed. De Gruyter, Berlin	No	
A7.1.1.1.1/04	Kemp, P.H.	1956	"The Chemistry of Borates Part 1", copyright	No	
A7.1.1.1.1/05	Maeda, M	1979	Raman spectra of polyborate ions in aqeous solution. J Inorg. Nucl. Chem. vol 41: 1217-1220 Non-GLP Published	No	
A7.1.1.1.1/06	Hanstveit A O	2004	Boric Acid (CAS No. 10043-35-3): Statement on Hydrolysis as a function of pH and identification of breakdown products TNO Report No V6004/05. Report to Borax Europe Limited Unpublished	Yes	BEU

Reference list of studies on the product

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B5.10/01	Cookson LJ and Pham K	1996	Relative tolerance of twenty basidiomycetes to boric acid. Mat und Org 29 (3) 187-196. Non-GLP Published	No	CSIRO

Reference list of literature and studies that where added to the dossier after submission of the summary dossier by the applicant

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Doc IIIA	Abou-Shakra, F.R., Havercroft, J.K. and Ward	1989	Lithium and Boron in Biological Tissues and Fluids. Trace Elements in Medicine 6, 142-146.	No	
Doc IIA	Adelhardt, M. and Fogh, A.	1983	Enquiries to a centre for information on poisoning during a period of 12 years (English translation). Boraks – er de farligt (12 ars foresporgslert il giftinformationscentralen) Ugeskr. Laeger. 145 3808 – 3810.	No	
	Adriano, D.C., Kaplan, D.I., Burkman, W.G. and Mills, G.L.	1988	Long-term phytoavailability of soil applied organo-borates. J. Environ. Qual. 17, 485-492.	No	
	AE	1998	Development of plant toxicity tests for assessment of contaminated soils. Orton, Canada: Aquaterra Environmental.	No	
Doc IIIA	Aitken, R.L, and McCallum, L.E.	1988	Boron toxicity in soil solution. Aust. J. Soil Res 26, 605-610.	No	
Doc IIIA	Alexander, G.V, Nusbaum, R.E. and MacDonald, N.S.	1951	The boron and lithium content of human bones, J. Biol. Chem. 192, 489-496.	No	
Doc IIIA	Allen, R. and Walker, A.	1987	The influence of soil properties on the rates of degradation of metamitron, metazachlor and metribuzin. Pest. Sci. 18, 95-111.	No	
Doc IIIA	Astier A., Baud, F. and Fourneir, A.	1988	Toxicokinetics of boron after an acute accidental intoxication by boric acid. J. Pharm. Clin. 7, 57-62.	No	
	BC.	1991	Boron for field crops. Soil Factsheet. British Columbia Ministry of Agriculture and Food, May 1991.	No	
Doc IIIA	Beavers, J.B.	1984	A dietary LC50 study in the Bobwhite with boric Acid - Final Report. St. Michaels, USA: Wildlife International Ltd., project no. 176-102a. (TX 1984067.pdf)	No	
	Beavers, J.B. and Fink, R.	1982a	Acute oral LD50 of POLYBOR – Bobwhite quail. St. Michaels, USA: Wildlife International Ltd., project no. 135-105.	No	
	Beavers, J.B. and Fink, R.	1982b	Eight-day dietary LC50 of POLYBOR – Bobwhite quail. St. Michaels, USA: Wildlife International Ltd., project no. 135-103.	No	
	Beavers, J.B. and Fink, R.	1982c	Eight-day dietary LC50 of POLYBOR – Mallard duck. St. Michaels, USA: Wildlife International Ltd., project no. 135-104.	No	
Doc IIA	Birge, W.J. and Black, J.A.	1977	Sensitivity of vertebrate embryos to boron compounds EPA-560/1-76-008, PB 267 085. Office of toxic substances, US EPA, Washington D.C. 20460, USA	No	
Doc IIA	Black, J.A., Barnum J.B. and Birge, W.J.	1993	An integrated assessment of the biological effects of boron to the rainbow trout. Chemosphere 26, 1383-1413.	No	
Doc IIIA	Bowen, J.E. and Gauch, H.G.	1966	Nonessentiality of boron in fungi and the nature of its toxicity. Plant Physiol. 41, 319-324.	No	
	Bremmer, H.J. and M.P. Van Veen	2000	Paint Fact Sheet, RIVM report nr. 612810 010 (in Dutch)	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
	Bringmann, G.	1978	Bestimmung der biologischen Schadwirkung wassergefährdender Stoffe gegen Protozoen. I. Bakterienfressende Flagellaten (Modelorganismus Entosiphon sulcatum Stein) Z. f. Wasser- und Abwasser Forsch. 11, 210-215.	No	
	Bringmann, G. and Kühn, R.	1976	Vergleichende Befunde der Schadwirkung wassergefährender Stoffe gegen Bakterien (Pseudomonas putida) und Blaualgen (Microcystis aeruginosa). Gwf-wasser/abwasser 117, H.9, 410-413	No	
	Bringmann, G. and Kühn, R.	1977a	Grenzwerte der Schadwirkung wassergefährdender Stoffe gegen Bakterien (Pseudomonas putida) und Grünalgen (Scenedesmus quadricauda) im Zellvermehrungshemmtest. Z. f. Wasser- und Abwasser-Forschung 10, 3/4, 87-98.	No	
	Bringmann, G. and Kühn, R.	1977b	Grenzwerte der Schadwirkung wassergefährdender Stoffe gegen Daphnia magna. Z. f. Wasser- und Abwasser-Forschung 10, 5, 161-166.	No	
	Bringmann, G. and Kühn, R.	1978a	Grenzwerte der Schadwirkung wassergefährdender Stoffe gegen Blaualgen (Microcystis aeruginosa) und Grünalgen (Scenedesmus quadricauda) im Zellvermehrungshemmtest. Vom Wasser 50, 45-60.	No	
	Bringmann, G. and Kühn, R.	1978b	Testing of substances for their toxicity threshold: model organisms Microcystis (diplocystis) aeruginosa and Scenedesmus quadricauda. Mitteilungen der Internationalen Vereinigung der Limnologie 21, 275-284. 78.	No	
	Bringmann, G. and Kühn, R.	1980a	Comparison of the toxicity thresholds of water pollutants to bacteria, algae, and protozoa in the cell multiplication inhibition test. Water Res. 14, 231-241.	No	
	Bringmann, G. and Kühn, R.	1980b	Bestimmung der biologischen Schadwirkung wassergefährdender Stoffe gegen Protozoen. II. Bakterienfressende Ciliaten. Z. f. Wasser- und Abwasser-Forsch. 13, 26-31.	No	
Doc IIA	Brown, T.F., McCormick, M.E., Morris, D.R. and Zeringue, L.K.	1989	Effects of dietary boron on mineral balance in sheep. Nutr. Res. 9, 503-521.	No	
Doc IIIA (sodium tetraborate)	Bruze, M., Hradil, E., Eriksohn, I-L., Gruvberger, B. and Widstrom, L.	1995	Occupational allergic contact dermatitis from alkanolamineborates in metalworking fluids. Contact Dermatitis 32, 24 -27.	No	
	Buchter, B., Davidoff, B., Amacher, M.C., Hinz, C., Iskandar, I.K. and Selim, H.M.	1989	Correlation of Freundlich Kd and n retention parameters with soils and elements. Soil Sci. 148, 370-379.	No	
Doc IIA	Butterwick, L., De Oude, N., Raymond, K.	1989	Safety assessment of boron in aquatic and terrestrial environments. Ecotoxicol. Environ. Saf., 17, 339-371.	No	
Doc IIIA (sodium tetraborate)	Cerven, D.R.	2000	Acute eye irritation on rabbits: EPA Reg. No 1624-1, Borax 5 mol., Sodium tetraborate penthydrate Lot #OE26. Study no MB 00-8677.04 MB Research Laboratories, Spinnerstown PA 18968. Unpublished report to US Borax (TX2000005.pdf)	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
	Chapin, R.E., Ku, W.W., Kenney, M.A., McCoy, H, Gladen, B., Wine, R.N., Wilson, R. and Elwell, M.R.	1997	The effects of dietary boron on bone strength in rats. Fundam. Appl. Toxicol. 35: 205-215.	No	
Doc IIIA	Ciba, J. and Chrusciel, A.	1992	Spectrophotometric determination of boron in human hair with Azomethine H. Fresenius J. Anal. Chem. 342, 147-149	No	
Doc IIIA	Cox, J.A., Lundquist, G.C., Przyjazmy, A. and Schmulback, C.D.	1978	Leaching of boron from coal ash. Environ. Sci. Technol. 12, 722-723.	No	
Doc IIIA	Crommentijn, G.H., Posthumus, R. and Kalf, D.F.	1995	Derivation of the ecotoxicological serious soil contamination concentration (Substances evaluated in 1993 and 1994). Bilthoven, The Netherlands: National Institute of Public Health and Environmental Protection, report no. 715810 008. Available from http://www.rivm.nl/bibliotheek/rapporten/715810008.pdf	No	
Doc IIIA	Culver, B.D., Shen, P., Taylor, T.H., Feldstein, A.L., Anton-Culver, H. and Strong, P.L.	1993	Absorption of boron by sodium borate and boric acid production worlers. Report to US Borax., August 11, 1993.	No	
Doc IIIA	Culver, B.D., Shen, P.T., Taylor, T.H., Lee-Feldstein, A., Anton-Culver, H. and Strong, P.L.	1994	The relationship of blood-and urine-boron to boron exposure in borax-workers and the usefulness of urine-boron as an exposure marker. Environ. Health Perspect. 102 (7), 133-137.	No	
Doc IIIA	Cuperus, L., Mazur, P., Stubblefield, S., Opsahl,W. and Robles, H.	1990	Evaluation of the Occular Irritation of Anhydrous Boric Acid in Rabbits. (P01875). Biological Test Center, Irvine, CA 92714. Unpublished report to US Borax. 25 April, 1990. (TX-90-001)	No	
	Datta, S.P. and Bhadoria, P.B.S.	1999	Boron adsorption and desorption in some acid soils of West Bengal, India. J. Plant Nutr. Soil Sci. 162, 183-191.	No	
	Davis, S.M., Drake, K.D. and Maier, K.J.	2002	Toxicity of boron to the duckweed, Spirodella polyrrhiza. Chemosphere 48, 615-620.	No	
Doc IIIA	De Vette, H.Q.M., Otto, C. and Schoonmade, J.A.	2001	A study on the identification and comparison of the dissociation products of Polybor tech., Borax, Manufacturing grade and Boric Acid, Manufacturing grade in aqueous solutions using Raman spectrometry. Delft, The Netherlands: TNO Nutrition and Food Research. TNO study no. IMW-99-9050-01, report no. V99.1153. File: TX20000013.pdf	No	
Doc IIIA	Denton, S.	1995	Final Report: Anhydrous Boric Acid. Acute Oral Toxicity Study in the Rat. Report number 1341/3-1032, Corning Hazleton (Europe), Harrogate, N Yorkshire, HG3 1PY, UK. Unpublished Report to Borax Europe Ltd. (TX-095-003)	No	

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Doc IIIA	Denton, S.	1996a	Final Report: Anhydrous Boric Acid. Acute Oral Toxicity Study in the Rat. Report number 1341/7-1032, Corning Hazleton (Europe), Harrogate, N Yorkshire, HG3 1PY, UK. Unpublished Report to Borax Europe Ltd. (TX-096-003)	No	
Doc IIIA (sodium tetraborate)	Denton, S.M.	1996b	Dehybor anhydrous Borax Acute Oral Study in the Rat. Corning Hazleton (Europe), Harrogate, N Yorkshire, HG3 1PY, Study No 1341/6-1032. Unpublished Report to Borax Europe Limited, March 1996 Study file name: TX1996001.pdf	No	
Doc IIIA	Dourson, M., Meier, A., Meek, B., Renwick, A., Ohanian, E. and Poirier, K.	1998	Boron tolerable intake: re-evaluation of toxicokinetics for data-derived uncertainty factors. Biol. Trace Elem. Res. 66 (1-3), 453-463.	No	
Doc IIIA (disodium octaborate tetrahydrate)	Doyle, R.L	1988	Hill Top Biolabs Inc., Main and Mill Streets, Miamiville, OH 45147, U.S.A., Acute Oral Toxicity in Rats; Median Lethal Dosage of 20 Mule Team TIM-BOR, Study No.88-3195-21. Unpublished Report to United States Borax and Chemical Corporation, 10 August 1988. Study file name: TX1988022.pdf	No	
Doc IIIA (disodium octaborate tetrahydrate)	Doyle, R.L.	1989a	Hill Top Biolabs Inc., Main and Mill Streets, Miamiville, OH 45147, USA., " Acute Dermal Toxicity in Rabbits of Disodium Octaborate Tetrahydrate", Study No. 88-3442-21 (A). Unpublished report to United States Borax and Chemical Corporation, 8 March 1989 (TX089-005).	No	
Doc IIIA (disodium octaborate tetrahydrate)	Doyle, R.L.	1989b	Hill Top Biolabs, Inc., Main and Mill Streets, Miamiville, OH 45147, U.S.A., "Primary Skin Irritation in Rabbits of Disodium Octaborate Tetrahydrate", Study No. 88-3442-21 (B). Unpublished report to United States Borax and Chemical Corporation, 21 February 1989 (TX089-004).	No	
Doc IIIA	Doyle, R.L.	1989c	Primary eye irritation of boric acid. Ref 88-3444-21 of 7 February 1989, Hill Top Biolabs Inc., Cincinnati, Ohio 45242 USA. (Unpublished report No. TX-089-006 to US Borax Chemical Corporation)	No	
Doc IIIA (disodium octaborate tetrahydrate)	Doyle, R.L.	1989d	Hill Top Biolabs, Inc., Main and Mill Streets, Miamiville, OH 45147, U.S.A., "Primary Eye Irritation in Rabbits of Disodium Octaborate Tetrahydrate", Study No. 88-3442-21 (C). Unpublished report to United States Borax and Chemical Corporation, 13 January 1989 (TX089-003).	No	
Doc IIIA	Draize, J.H. and Kelley, E.A.	1959	The urinary excretion of boric acid preparations following oral administration and topical applications to intact and damaged skin of rabbits. Toxicol. Appl. Pharmacol. 1, 267-276	No	
Doc IIA	Dyer, S.D.	2001	Determination of the aquatic PNEC0.05 for boron. Chemosphere 44, 369-376	No	
	Eaton, F.M.	1944	Deficiency, toxicity, and accumulation of boron in plants. J. Agric. Res. 69, 237-277.	No	
	EBA.	2005	E-mail message from EBA (Sue Hubbard) to CTB (Annette Smits), May 9th 2005. EBA PT 8 Tier1 RA, May 2005, Final update xls.	No	
	EBA.	2005	E-mail message from EBA (Sue Hubbard) to CTB (Annette Smits), May 11th 2005. HH Exposure Update, CTB 11-05-05 xls.	No	
	EBA.	2005	E-mail message from EBA (Sue Hubbard) to CTB (Annette Smits), June 9th 2005. First reply to CTB.	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
	EC.	2002	Technical Notes for Guidance (TNsG). Human Exposure to Biocidal Products – Guidance on Exposure Estimation. Contract B4-3040/2000/291079/MAR/E2. DG Environment June 2002. User Guidance, Version 1 belonging to Report Human Exposure to Biocidal Products (TNsG June 2002). Available from http://ecb.jrc.it/	No	
	EC.	2003	Technical Guidance Document on risk assessment in support of Commission Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulation (EC) No 1488/94 on risk assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. Ispra, Italy: European Commission Joint Research Centre.	No	
	EC.	2004	European Union System for the Evaluation of Substances 2.0 (EUSES 2.0). Prepared for the European Chemicals Bureau by the National Institute of Public Health and the Environment (RIVM), Bilthoven, The Netherlands. Available via the European Chemicals Bureau, http://ecb/jrc/it	No	
Doc IIA	ECETOC	1997	Ecotoxicology of some Inorganic Borates. Brussels, Belgium: European Centre for Ecotoxicology and Toxicology of Chemicals, Special Report No. 11.	No	
Doc IIA	Eisler, R.	1990	Boron hazards to fish, wildlife and invertebrates: a synoptic review. Contaminant Hazard Reviews, Report 20. Maryland, USA: US Fish and Wildlife Service, biological report 85 (1.20), April 1990, 32 pp. Available at www.pwrc.usgs.gov/contaminants/ under "Contaminant Hazard Reviews On-Line.	No	
	Elrashidi, M.A. and O'Connor, G.A.	1982	Boron sorption and desorption in soils. Soil Sci. Sco. Am. J. 46, 27-31.	No	
Doc IIIA	Emsley, J.	1989	The Elements. Clarendon, Oxford, p. 32.	No	
	EPFL.	2003	Research in support of the Environment Canada collembolan toxicity test method with Folsomia candida for assessment of contaminated soils. Final report. Lausanne, Switzerland: Ecole Polytechnique Fédérale de Lausanne (EPFL).	No	
	Ernst, W.H.O.	1990	Mine vegetation in Europe. In: Heavy metal tolerance in plants: Evolutionary aspects (Shaw, A.J. ed.), pp. 21-37. Boca Raton, FL: CRC Press.	No	
	ESG	2003	Assessment of the biological test methods for terrestrial arthropods: further refinement of the Collembola test method using Onychiurus folsomi. Guelph, Ontario: ESG International Inc.	No	
Doc IIIA	Farr, L.E. and Konikowski, T.	1963	The renal clearance of sodium pentaborate in mice and men. Clin. Chem. 9, 717-726.	No	
Doc IIIA	Forbes, R.M. and Mitchell, H.H.	1957	Accumulation of dietary boron and strontium in young and adult albino rats. Arch. Ind. Health 16, 489-492.	No	
Doc IIA	Forbes, R.M., Cooper, A.R. and Mitchell, H.H.	1954	On the occurrence of beryllium, boron, cobalt, and mercury in human tissues. J. Biol. Chem. 209, 857-864.	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Doc IIIA	Friis-Hansen, B., Aggerbeck, B. and Jansen, J.A.	1982	Unaffected blood boron levels in new-born infants treated with a boric acid ointment, Fd. Chem. Toxicol. 20, 451.	No	
	Garabrant, D.H., Bernstein,L. Peters, J.M. and Smith T.J.	1984	Respiratory and eye irritation from boron oxide and boric acid dusts. J. Occup. Med. 26 : 584-586.	No	
	Garabrant, D.H., Bernstein,L. Peters, J.M., Smith T.J. and Wright, W.E.	19851984	Respiratory effects of borax dusts. J. Occup. Med. 26, 584-586.	No	
	Gersich, F.M.		Evaluation of a static renewal chronic toxicity test method for Daphnia magna Straus using boric acid. Environ. Toxicol. Chem. 3, 89-94.	No	
	Gestring, W.D. and Soltanpour, P.N.	1987	Comparison of soil tests for assessing boron toxicity to alfalfa. Soil Sci. Soc. Am. J. 51, 1214-1219.	No	
	Gladney, E.S., Wangen, L.E., Curtis, D.R. and Jurney, E.T.	1978	Observations on boron release from coal-fired power plants. Environ. Sci. technol. 12, 1084-1085.	No	
	Goldberg, S.	1997	Reactions of boron with soils. Plant and Soil 193, 35-48.	No	
	Grella, P., Tambuscio, B. and Suma, V.	1976	Boric acid and poisoning during pregnancy: Description of one case. Acta Anaestesiol. Ital. 27: 745-748 (in Italian).	No	
	Guhl, W.	1992	Ökologische Aspekte von Bor. Vertrag gehalten anlässlich der 39. Sepawa-Jahrestagung 1992 in Bad Dürkheim. SÖFW-Journal, 18, 3-10.	No	
Doc IIA	Guhl, W.	1996	Ecological aspects of boron. SÖFW-Journal 118, 1159-1168.	No	
Doc IIIA	Gupta, U. and Cutcliffe, J.A.	1984	Effects of applied and residual boron on the nutrition of cabbage and field beans. Can. J. Soil Sci. 64, 571-576.	No	
Doc IIA	Gupta, U.C., Jame, Y.W., Campbell, C.A., Leyshon, A.J. and Nicholaichuk, W.	1985	Boron toxicity and deficiency: a review. Can. J. Soil Sci. 65, 381-409.	No	
Doc IIA	Hamilton, S.J. and Buhl, K.J.	1997	Hazard evaluation of inorganics, singly and in mistures, to Flannelmouth Sucker Catostomus latipinnis in the San Juan River, New Mexico. Ecotox. Environ. Saf. 38, 296-308	No	
Doc IIIA	Hanstveit, A.O. and H. Oldersma.	2000	Determination of the effect of Boric Acid, Manufacturing Grade on the growth of the fresh water green alga, Selenastrum capricornutum. Delft, The Netherlands: TNO Nutrition and Food Research Institute. TNO study no. IMW-99-9047-05. Study file name: TX2000007.pdf	No	
Doc IIIA	Hanstveit, A.O. and Schoonmade, J.A.	2000	Screening of the effect of Boric Acid, Manufacturing Grade on the respiration rate of activated sludge. Delft, The Netherlands: TNO Nutrition and Food Research Institute. TNO study no. IMW-99-9047-06.	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Doc IIA	Heindel, J.J., Price, C.J., Field, E.A., Marr, M.C., Myers, C.B., Morrissey, R.E. and Schwetz, B.A.	1992	Developmental toxicity of boric acid in mice and rats, Fund. Appl. Toxicol. 18, 266-272.	No	
Doc IIIA	Henzen, L.	2000	The acute toxicity of Boric Acid, Manufacturing Grade to the worm species, Eisenia fetida in a 14d test. Delft, The Netherlands: TNO Nutrition and Food Research Institute. TNO study no. IMW-99-9047-07. Study file name: TX20000008.pdf.	No	
	Hickey, C.W.	1989	Sensitivity of four New Zealand cladoceran species and Daphnia magna to aquatic toxicants. New Zealand J. Mar. Fresh. Res. 23, 131-137.	No	
Doc IIIA	Hooftman, R.N., Van Drongelen-Sevenhuijsen, D. and De Haan, H.P.M.	2000a	Semi-static reproduction test with Boric Acid, Manufacturing Grade and Daphnia magna. Delft, The Netherlands: TNO Nutrition and Food Research Institute. TNO study no. IMW-99-9047-10. Study file name: TX2000009.pdf	No	
Doc IIIA	Hooftman, R.N., Van Drongelen-Sevenhuijsen, D. and De Haan, H.P.M.	2000b	Early life stage test under semi-static conditions with boric acid, manufacturing grade and the zebra fish Brachydanio rerio (OECD Guideline no. 210). Delft, The Netherlands: TNO Nutrition and Food Research Institute. TNO study no. IMW-99-9047-09. Study file name: TX2000010.pdf	No	
Doc IIIA	Hui, X., Wester, R.C. and Maibach, H.I.	1996	In Vivo Percutaneous Absorption of Boric Acid, Borax and Octaborate Tetrahydrate (DOT) in Man. Unpublished Report to U.S. Borax Inc., Study Number H832-11830-01, November 12.	No	
Doc IIIA	Jansen, J.A., Schou, J.S. and Aggerbeck, B.	1984a	Gastrointestinal absorption and in vitro release of boric acid from water-emulsifying ointments, Fd. Chem. Toxicol. 22, 49-53.	No	
Doc IIIA	Jansen, J.A., Andersen, J. and Schou, J.S.	1984b	Boric acid single dose pharmacokinetics after intravenous administration to man, Arch. Toxicol. 55, 64-67.	No	
Doc IIIA	Job, C.	1973	Absorption and excretion of orally administered boron, Z. Angew. Bader-und Klimaheilkunde 20, 137-142.	No	
	Kartal, S.N. and Green, F.	2003	Leachability of boron from wood treated with natural and semi-synthetic polymers and calcium precipitating agent. Holz als Roh- und Werkstoff 61, 388-389.	No	
	Kartal, S.N. and Imammura, Y.	2004	Effects of N'-N-(1,8-naphthalyl) hydroxylamine (NHA-Na) and hydroxynaphthalimide (NHA-H) on boron leachability and biological degradation of wood. Holz als Roh- und Werkstof, 62, 378-385.	No	
Doc IIIA	Keller, J.G.	1962	Boric acid. Acute oral administration – Rats. Final report, March 19th. Falls Church, USA: Hazleton Laboratories Inc. Study filename: TX-62-5	No	
	KEMI	1991	Ecotoxicological evaluation of boron compounds used as wood preservatives. Solna, Sweden: National Chemicals Inspectorate.	No	
	Kjølholt, J., Stuer-Lauridsen, F., Skibsted Mogensen, A. and Havelund, S.	2003	The Elements in the Second Rank - an environmental problem now or in the future? Kopenhagen, Denmark: Danish Environmental Protection Agency, Environmental Project No. 770. Available from: http://www mst.dk/udgiv/publications/2003/87-7972-491-4/html/bill01 eng htm	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
	Kopf, W. and Wilk, A.	1995	Investigation on aquatic toxicity against plant organisms. Munich, Germany, Institute for Water Research (unpublished report).	No	
Doc IIIA	Ku, W.W., Chapin, R.E., Moseman, R.F., Brink, R.E., Pierce, K.D. and Adams, K.Y.	1991	Tissue disposition of boron in male Fischer rats. Toxicol. Appl. Pharmacol. 111, 145-151.	No	
Doc IIIA	Ku, W.W., Chapin, R.E., Wine, R.N. and Gladen, B.C.	1993	Testicular toxicity of boric acid (BA): Relationship of dose to lesion development and recovery in the F344 rat. Reprod. Toxicol. 7, 305-319.	No	
Doc IIIA	Laurent-Pettersson, M., Delpech, B. and Thellier, M.	1992	The mapping of natural boron in histological sections of mouse tissues by the use of neutron capture radiography. Histochem. J. 24, 939-950.	No	
	Lewis, M.A. and Valentine, L.C.	1981	Acute and chronic toxicities of boric acid to Daphnia magna Straus. Bull. Environ. Contam. Toxicol. 27, 309-315.	No	
	Liang, C.N. and Tabatabai, M.A.	1977	Effects of trace elements on nitrogen mineralisation in soils. Environ. Pollut. 12, 141-147.	No	
Doc IIIA	Litovitz, T.L., Klein-Schwartz, W., Oderda, G.M. and Schmitz, B.F.	1988	Clinical manifestations of toxicity in a series of 784 boric acid ingestions. Am. J. Emerg. Med. 6, 209-213.	No	
Doc IIIA	Locksley, H.B. and Sweet.	1954	Tissue distribution of boron compounds in relation to Neutron-capture Therapy of cancer. Proc. Soc. Exp. Biol. Med. 86, 56-63.	No	
Doc IIA	Loewengart, G.	2001	Toxicity of boron to rainbow trout: a weight-of-the-evidence assessment. Environ. Toxicol. Chem. 20, 796-803.	N	
Doc IIIA	Maier, K.J. and Knight, A.W	1991	The toxicity of waterborne boron to Daphnia magna and Chironomus decorus and the effects of water hardness and sulfate on boron toxicity. Arch. Environ. Contam. Toxicol. 20, 282-287.	No	
Doc IIIA	Massie, H.R., Aiello, V.R., Shumway, A.E. and Armstrong, T	1990	Calcium, iron, boron, collagen and density changes in bone with aging in C57BL/65 mice. Exp. Gerontol. 469-481	No	
Doc IIIA (sodium tetraborate)	Meyding, G.D. and Foglhian, R.W.	1961	10-Mol Borax. Acute Oral Administration (rats). Hazleton Nuclear Science Corporation, Palo Alto Ca 67500. Unpublished Report to US Borax (TX-61-5), August 2, 1961 Study file name: TX1961005	No	
	Miljøstyrelsen	1996	Leaching of copper, boron and tebuconazole from wood impregnated with Tanalith 3491. Reference VM/LK/11, 25 November 1996 (in Danish).	No	
Do IIIA	Minoia, C., Sabbioni, E., Apostoli, P., Pietra, R., Pozzoli, L., Gallorini, M., Nicolaou, G., Alessio, L. and Capodaglio, E	1990	Trace element reference values in tissues from inhabitants of the European Community 1. A study of 46 elements in urine, blood and serum of Italian subjects. Sci. Total Environ. 95, 89-105.	No	

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Doc IIA	Minoia, C., Sabbioni, E., Ronchi, A., Gatti, A., Pietra, A.	1994	Trace element reference values in tissues from inhabitants of the European Community. IV. Influence of dietary factors. Sci. Total Environ. 141, 181-195.	No	
Doc IIIA	Murray, F.J.	1998	A comparative review of the pharmacokinetics of boric acid in rodents and humans. Biol. Trace Elem. Res. 66:331-341.	No	
Doc IIIA	Nielsen, G.H.	1970	Percutaneous absorption of boric acid form boron-containing preparations in rats. Acta. Pharmacol. Toxicol. 28, 413-424.	No	
Doc IIIA	NTP	1987	Toxicology and carcinogenesis studies of boric acid (CAS No. 10043-35-3) in B6C3F1 mice. National Toxicology Program, US Department of Health and Human Services, National Institute of Health (Technical Report Series No. 324).	No	
	OECD	2000	OECD Guideline for the testing of chemicals. Adsorption – desorption using a batch equilibrium method. Section 1: Physical chemical properties. Method 106, adopted 21 January 2000.	No	
	OECD	2003	Emission Scenario Document for wood preservatives. OECD Series on Emission Scenario Documents, number 2. Paris, France: Organisation for Economic Co-operation and Development.	No	
Doc IIA	O'Sullivan, K and Taylor, M.	1983	Chronic boric acid poisoning in infants, Arch. Dis. Childhood 58, 737-749.	No	
Doc IIIA	Owen, E.C	1944	The excretion of borate by the dairy cow. J Dairy Res. 13, 243-248.	No	
Doc IIIA	Pahl, M.V., Culver, B.D. Strong, P.L., Murray F.J. and Vaziri, N.	2001	The effect of pregnancy on renal clearance of boron in humans: A study based on the normal dietary intake of boron. Toxicological Science 60, 252-256.	No	
	Paynter, O.E.	1963a	90 Day Dietary Feeding -- Dogs. Boric Acid. Hazleton Laboratories. Report TX-63-2. January 17, 1963. Unpublished.	No	
	Paynter, O.E.	1963b	90 Day Dietary Feeding -- Dogs. Borax. Hazleton Laboratories. Report TX-63-1. January 17, 1963. Unpublished.	No	
Doc IIIA	Price, C.J., Marr, M.C. and Myers, C.B.	1994	Determination of the no-observable-adverse-effect-level (NOAEL) for developmental toxicity in Sprague-Dawley (CD) rats exposed to boric acid in feed on gestational days 0-20, and evaluation of postnatal recovery through postnatal day 21. Report No. 65C-5657-200, Volume I-III, Research Triangle Institute, Research Triangle Park, NC. Unpublished Report to US Borax	No	
Doc IIIA	Price, C.J., Marr, M.C., Myers, C.B., Heindel, J.J. and Schwetz, B.A.	1991	Final report on the developmental toxicity of boric acid (CAS No 10043-35-3) in New Zealand white rabbits, TER-90003, NIEHS/NTP Order No. PB92-129550.	No	
	Raymond, K. and Butterwick, L.	1992	Perborate. In: The handbook of environmental chemistry, Volume 3, part F: Anthropogenic Compounds: Detergents, N.T. de Oude (ed.). Berlin, Heidelberg, Germany: Springer Verlag, pp. 287-318.	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Doc IIIA (sodium tetraborate)	Reagan, E.L. and Becci, P.J.	1985a	Acute oral LD50 study of 20 Mule Team, lot No. USB-12-84 sodium tetraborate pentahydrate in Sprague-Dawley rats. Food & Drug Research Laboratories, Inc., Waverly, NY 14892-0107, USA. (Unpublished report TX-85-5 of 1 February 1985 to U.S. Borax).	No	
Doc IIIA (sodium tetraborate)	Reagan, E.L. and Becci, P.J.	1985b	Acute dermal toxicity study of 20 Mule Team lot no. USB-12-84 sodium tetraborate pentahydrate in New Zealand white rabbits. Food and Drug Research Laboratories Inc., Waverly, NY 14892, Unpublished report to US Borax (TX85-6).	No	
Doc IIIA (sodium tetraborate)	Reagan, E.L. and Becci, P.J.	1985c	Acute dermal toxicity study of 20 Mule Team lot no. USB-11-84 sodium tetraborate decahydrate in New Zealand white rabbits. Food and Drug Research Laboratories Inc., Waverly, NY 14892, Unpublished report to US Borax (TX85-7)	No	
Doc IIIA (sodium tetraborate)	Reagan, E.L. and Becci, P.J.	1985d	Primary dermal irritation study of 20 Mule Team lot no. USB-12-84 sodium tetraborate pentahydrate in New Zealand white rabbits. Food and Drug Research Laboratories Inc., Waverly, NY 14892. Unpublished report to US Borax).	No	
Doc IIIA (sodium tetraborate)	Reagan, E.L. and Becci, P.J.	1985e	Primary dermal irritation study of 20 Mule Team , lot no. USB-11-84 sodium tetraborate decahydrate in New Zealand white rabbits. Food & Drug Research Laboratories Inc., Waverly, NY 14892-0107, USA. (Unpublished report TX-85-8 of 23 January 1985 to U.S. Borax Research Corp).	No	
	Reagan, E.L. and Becci, P.J.	1985f	Primary eye irritation study of 20 Mule Team lot no. USB-11-84 sodium tetraborate decahydrate in New Zealand white rabbits. Food and Drug Research Laboratories Inc., Waverly, NY 14892. Unpublished report to US Borax.	No	
	Riley, M.M.	1987	Boron toxicity in barley. J. Plant Nutr. 10: 2109-2015.	No	
Doc IIIA	Riley, M.M., Robson, A.D., Dellar, G.A. and Gartrell, J.W.	1994	Critical Toxic Concentrations of boron are variable in barley. J. Plant Nutrition 17, 1701-1719.	No	
	Rogers, J.E. and Li, S.W.	1985	Effect of metals and other inorganic ions on soil microbial activity: soil dehydrogenase assay as a simple toxicity test. Bull. Environ. Contam. Toxicol. 34, 858-865.	No	
	Rose, E.F., Carignan, J. and Chaussidon, M.	2000	Transfer of atmospheric boron from oceans to the continents: an investigation using precipitation waters and epiphytic lichens. Geochem. Geophys. Geosyst. 1, paper number 2000GC000077, published November 10, 2000.	No	
Doc IIIA	Rudd, C.J.	1991	Mouse lymphoma cell mutagenesis assay of Boric Acid. SRI International. Study No. 2389-G300-91, 23 August 1991, Menlo Park, CA.	No	
Doc IIIA	Sabbioni, E., Nicolaou G.R., Pietra, R., Beccaloni, E., Conni, E., Alimonti, A. and Caroli, S.	1990	Inductively coupled atomic emission spectrometry and neutron activation analysis for the determination of element reference values in human lung tissue. Biological Trace Element research, 26-27, 757-768.	No	
	Saiki, M.K., Jennings, M.R., Brumbaugh, W.G.	1993	Boron, Molybdenum, and Selenium in aquatic food chains from the lower San Joaquin river and it tributaries, California. Arch. Environ. Contam. Toxicol. 24, 307-319	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Doc IIIA	Sayli, B.S.	1998	Assessment of fertility and infertility in boron-exposed Turkish subpopulations. Pt. 2. Vidence that Boron has no effect on human reproduction, Biol. Trace Elem. Res. 66, 406-422	No	
	Schöberl, P., Huber, L.	1988	Ecologically relevant data of non-tenside compounds in detergents and cleaners. Tenside Deterg. 25: 99-107	No	
	Schoknecht, U., Mathies, H., Wegner, R., Melcher, E., Seidel, B., Kussatz, C.	2004	The influence of test parameters on the emission of biocides from preservative-treated wood in leaching tests. Umweltforschungsplan des Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit. Förderkennzeichen (UFOPLAN) 203 67 441, Germany.	No	
Doc IIIA	Schou, J.S., Jansen, J.A. and Aggerbeck, B	1984	Human pharmacokinetics and safety of boric acid, Arch. Toxicol. 7, 232-235.	No	
Doc IIIA	Shuler, T.R., Pootrakul, P., Yamsukon, P. and Nielsen F.H.	1990	Effect of thalassemia/haemoglobin E disease on macro, trace and ultratrace element concentrations in human tissue. J. Trace Elem. Exp. Med. 3, 31-43	No	
	Singh, M.	1971	Equilibirum adsorption of boron in soils and clays. Geoderma 5, 209-217.	No	
	Sprague, R.W.	1972	The ecological significance of boron. Los Angelos, USA: United States Borax and Chemical Corp., 68 pp.	No	
	STANTEC/AEC	2003	Assessment of the biological test methods for invertebrates: further refinement of the test method using Eisenia andrei. Guelph/Orton, Canada: Stantec Consulting Ltd./Aquaterra Environmental Consulting, Ltd., Report no. 62679096.	No	
Doc IIIA	Stewart, K.R.	1991	Salmonella/microsome plate incorporation assay of boric acid. SRI International, Menlo Park, CA, Study No. 2389-A200-91, Unpublished report to US Borax (TX091-008).	No	
Doc IIIA	Stüttgen, G., Siebel, Th., and Aggerbeck, B.	1982	Absorption of Boric Acid through Human Skin Depending on the Type of Vehicle. Arch Dermatol Res. 272: 21-29.	No	
	Suloway, J.J., Roy, W.R., Skelly, T.M., Dickerson, D.R., Schuller, R.M. and Griffin, R.A.	1983	Chemical and toxicological properties of coal fly ash. Champaign, Illinois, Illiniois State Geological Survey (Publication NTIS PB84-116110).	No	
Doc IIIA	Sutherland, B., Strong, P.L. and King, J.C.	1998	Determining Human Dietary Requirements for Boron. Biological Trace Element Research. 66, 193-204.	No	
	SYKE	1998a	Ecotoxicological risk assessment of the wood preservative TIM-BOR. Helsinki, Finland: Finnish Environment Institute (SYKE).	No	
	SYKE	1998b	Ecotoxicological risk assessment of the wood preservative Jerbor. Helsinki, Finland: Finnish Environment Institute (SYKE).	No	
	SYKE	2002	Addendum to the ecotoxicological evaluation of boric acid in TIM-BOR based on the data submitted by Borax Europe Limited. Helsinki, Finland: Finnish Environment Institute (SYKE).	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
	Thevenon, M-F., Pizzi, A., Halluk, J-P.	1998	Condensed tannins and boric acid for environment friendly wood preservatives. Poster at the 2nd international electronic conference on synthetic organic chemistry (ECSOC-2). http://ecsoc2 hcc ru/DP_TOP5/dp263/dp263 htm	No	
	Thompson, J.A.J., Davis, J.C. and Drew. R.E.	1976	Toxicity, uptake and survey studies of boron in the marine environment. Wat. Res. 10, 869-875.	No	
	Traas, T.P. (ed.).	2001	Guidance document on deriving environmental risk limits. Bilthoven, The Netherlands: National Institute of Public Health and the Environment, report no. 601501012. Available from http://www rivm.nl/bibliotheek/rapporten/601501012.pdf	No	
Doc IIIA	Treinen K.A. and Chapin, R.E.	1991	Development of testicular lesions in F344 rats after treatment with boric acid, Toxicol. Appl. Pharmacol. 107, 325-335.	No	
Doc IIIA	Usuda, K., Kono, K., Orita, Y., Dote, T., Iguchi, K., Nishiura, H., Tominga, M., Tagawa, T., Goto, E., and Shirai, Y.	1998	Serum and urinary boron levels in rats of sodium tetraborate. Arch. Toxicol. 72, 468-474.	No	
Doc IIA	Van de Plassche, E., Van de Hoop, M., Posthumus, R. and Crommentuijn, T.	1999	Risk limits for boron, silver, titanium, tellurium, uranium and organosilicon compounds in the framework of EU Directive 76/464/EEC. Bilthoven, The Netherlands: National Institute of Public Health and the Environment, report no. 601501005. Available from http://www rivm.nl/bibliotheek/rapporten/601501005.pdf	No	
	Van Dijk, W.	2003	Adviesbasis voor de bemesting van akkerbouw- en vollegrondsgroentegewassen. Wageningen, The Netherlands: Praktijkonderzoek Plant en Omgeving B.V., report no. 307 (in Dutch).	No	
	Vanderpool, R.A., Haff, D. and Johnson, P.E.	1994	Use of inductively coupled plasma-mass s[pectometry in boron – 10 stable isotope experiments with plants rats and humans. Environ. Health Perspect. 102 (Suppl 7), 13-20.	No	
	Van Vlaardingen, P.L.A., Traas, T.P., Wintersen, A.M. and Aldenberg, T	2004	ETX 2.0. A program to calculate hazardous concentrations and fraction affected, based on normally distributed toxicity data. Bilthoven, The Netherlands: National Institute for Public Health and the Environment (RIVM). Report no. 601501028/2004, 68 pp. Available from http://www rivm.nl/bibliotheek/rapporten/601501028.pdf	No	
	Van Raaij, .M.T.M., Van Apeldoorn, M.E., Van Veen M.P. and Janssen, P.C.J.M.	1998	Public Health Risk Assessment of CCA-Products, RIVM/CSR advisory report 05723A01, April 8th 1998	No	

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Doc IIIA	Vaziri, N.D., Oveisi, F., Culver, B.D., Pahl, M.V., Anderson, M.E., Strong, P.L. and Murray, F.J.	2001	The effect of pregnancy on renal clearance of boron in rats given boric acid orally. Toxicological Science 60, 257-263.	No	
Doc IIIA	Ward, N.L.	1987	The determination of boron in biological materials by neutron irradiation and prompt gamma-ray spectrometry, J. Radioanal. Nucl. Chem. 110(2), 633-639.	No	
Doc IIIA	Weeth H.J., Speth, C.F. and Hanks, D.R.	1981	Boron content of plasma and urine as indicators of boron intake in cattle. Am. J. Vet. Res. 42, 474-477	No	
Doc IIA	Wegman, D.H., Eisen, E.A., Hu, X., Woskie, S., Smith R.G. and Garabant, D.H.	1994	Acute and chronic respiratory effects of sodium borate particulate exposures, Environ. Health Perspect. 102, 119-128.	No	
Doc IIIA	Weiner, A.S, Conine, D.L. and Doyle, R.L.	1982	Acute dermal toxicity screen in rabbits; Primary skin irritation study in rabbits of boric acid. Ref. 82-028021 of 15 March 1982, Hill Top Research, Inc., Cincinnati, Ohio.	No	
Doc IIIA	Weir, R.J.	1966a	Two-year dietary feeding study - albino rats. Boric acid. Final Report. Hazleton Laboratories Inc., Falls Church, VA, July 8th, 1966 (TX-66-18) and Addendum to Final Report, April 10, 1967 (TX-67-6) Unpublished report to US Borax Research Corporation	No	
Doc IIIA	Weir, R.J.	1966b	Two-year dietary feeding study – albino rats. Borax (Sodium tetraborate decahydrate). Final Report (TX-66-21). Hazleton Laboratories Inc., Falls Church, VA, July 8th, 1966 and Addendum to Final Report, April 10, 1967(TX-67-9). Unpublished report to US Borax Research Corporation	No	
Doc IIIA	Wester, R.C., Hui, X., Hartway, T., Maibach, H.I., Bell, K., Schell, M.J., Northington, D.J., Strong, P. and Culver, B.D.	1998	In vivo percutaneous absorption of boric acid, Borax and disodium octaborate tetrahydrate in humans compared to in vitro absorption in human skin from infinite to finite doses. Toxicol Sciences 45, 42-51.	No	
Doc IIA	WHO	1998	Environmental Health Criteria 204. Boron. Geneva, Switzerland: World Health Organization, International Programme on Chemical Safety.	No	
Doc IIA	Whorton, M.D., Haas, J.L., Trent, L. and Wong, O.	1994	Reproductive effects of sodium borates on male employees: birth rate assessment, Occup. Environ. Med. 51, 761-767.	No	
Doc IIIA	Wilding, J.L., Smith, W.J., Yevitch, P., Sicks, M.E., Ryan, S.G. and Punte, C.L.	1959	The toxicity of boron oxide. Am. Ind. Hyg. J 20, 284-289.	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Doc IIIA	Wnorowski, G.	1994a	Acute inhalation toxicity limit test on boric acid. Product Safety Labs, US, East Brunswick, New Jersey, 0881; Study - 3311. Unpublished report to U.S. Borax. Study file name: TX1994009.pdf	No	
Doc IIIA (sodium tetraborate)	Wnorowski, G.	1994b	Acute inhalation toxicity limit on disodium tetraborate decahydrate. Test Product Safety Labs, US, East Brunswick, New Jersey, 08816, Study - 3309. Unpublished report to U.S. Borax. Study file name: TX1994007.pdf	No	
Doc IIIA (sodium tetraborate)	Wnorowski, G.	1994c	Acute inhalation toxicity limit on disodium tetraborate pentahydrate. Test Product Safety Labs, US, East Brunswick, New Jersey 08816, Study - 3307. Unpublished report to U.S. Borax	No	
Doc IIIA (disodium octaborate tetrahydrate)	Wnorowski, G.	1994d	Acute inhalation toxicity limit on disodium octaborate tetrahydrate. Test Product Safety Labs, US, East Brunswick, New Jersey 08816, Study - 3313. Unpublished report to U.S. Borax.	No	
Doc IIIA	Wnorowski, G.	1994e	Dermal sensitization test - Buehler method on boric acid, Study - 3310. Product Safety Labs, East Brunswick, NJ 08816. Unpublished report to US Borax.	No	
Doc IIIA (sodium tetraborate)	Wnorowski, G.	1994f	Dermal sensitization test – Buehler method on sodium tetraborate decahydrate, Study - 3308. Product Safety Labs, East Brunswick, NJ 08816. Unpublished report to US Borax.	No	
Doc IIIA (sodium tetraborate)	Wnorowski, G.	1994g	Dermal sensitization test – Buehler method on sodium tetraborate pentahydrate, Study - 3306. Product Safety Labs, East Brunswick, NJ 08816. Unpublished report to US Borax.	No	
Doc IIIA (disodium octaborate tetrahydrate)	Wnorowski, G.	1994h	Dermal sensitzation test – Beuhler method on disodium octaborate tetrahydrate, Product Safety Labs, US, East Brunswick, New Jersey, 08816, Study No 3312, Unpublished Report to US Borax	No	
Doc IIIA	Wnorowski, G.	1997	Acute inhalation toxicity limit on boric acid MG Test Product Safety Labs, US, East Brunswick, New Jersey 08816, Study - 5257. Unpublished report to U.S. Borax	No	
Doc IIIA	Wong, L.C., Heimbach, M.D., Truscott, D.R. and Buncan, B.D.	1964	Boric acid poisoning: report of 11 cases. Canad. Med. Assoc. J. 90, 1018-1023.	No	
	Wyness, A.J., Parkman, R.H. and Neal, C	2003	A summary of boron surface water quality data throughout the European Union. Sci. Total Environ. 314-316, 255-269	No	
Doc IIIA	Young, J.A., Briggs, B.G. and Doyle, R.L.	1973	Corrosivity study on a series of ten materials. 73-630-21, Hill Top Research Inc., Cincinnati, Ohio, 45242. Unpublished report to US Borax	No	

Appendix IV: List of standard terms and abbreviations

Stand. term / Abbreviation	**Explanation**
A	ampere
ACh	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADME	administration distribution metabolism and excretion
ADP	adenosine diphosphate
AE	acid equivalent
AF	assessment factor
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD_{50}	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
Ann.	Annex
AOEL	acceptable operator exposure level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BAF	bioaccumulation factor
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
BPD	Biocidal Products Directive
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathy
BSP	bromosulfophthalein

Stand. term / Abbreviation	**Explanation**
Bt	*Bacillus thuringiensis*
Bti	*Bacillus thuringiensis israelensis*
Btk	*Bacillus thuringiensis kurstaki*
Btt	*Bacillus thuringiensis tenebrionis*
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10^{-2})
°C	degrees Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DANN
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
d	day(s)
DES	diethylstilboestrol
DIS	draft international standard *(ISO)*
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days post inoculation

Stand. term / Abbreviation	**Explanation**
DRP	detailed review paper *(OECD)*
$DT_{50(lab)}$	period required for 50 percent dissipation (under laboratory conditions) (define method of estimation)
$DT_{90(field)}$	period required for 90 percent dissipation (under field conditions) (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient
EC_{50}	median effective concentration
ECD	electron capture detector
ED_{50}	median effective dose
EDI	estimated daily intake
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EN	European norm
EPMA	electron probe micro-analysis
ERL	extraneous residue limit
ESPE46/51	evaluation system for pesticides
EUSES	European Union system for the evaluation of substances
F	field
F_0	parental generation
F_1	filial generation, first
F_2	filial generation, second
FBS	full base set
FELS	fish early-life stage
FIA	fluorescence immuno-assay
FID	flame ionisation detector
F_{mol}	fractional equivalent of the metabolite´s molecular weight compared to the active substance

Stand. term / Abbreviation	**Explanation**
FOB	functional observation battery
f_{oc}	organic carbon factor (compartment dependent)
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram(s)
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GMO	genetically modified organism
GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPS	global positioning system
GSH	glutathione
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value)
ha	hectare(s)
Hb	haemoglobin
HC5	concentration which will be harmless to at least 95 % of the

Stand. term / Abbreviation	**Explanation**
	species present with a given level of confidence (usually 95 %)
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionisation detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H_S	Shannon-Weaver index
Ht	haematocrit
HUSS	human and use safety standard
I	indoor
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilisation concentration or median inhibitory concentration 1
ICM	integrated crop management
ID	ionisation detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
INT	2-p-iodophenyl-3-p-nitrophenyl-5-phenyltetrazoliumchloride testing method
ip	intraperitoneal
IPM	integrated pest management
IR	infrared

Stand. term / Abbreviation	**Explanation**
ISBN	international standard book number
ISSN	international standard serial number
IUCLID	International Uniform Chemical Information Database
iv	intravenous
IVF	*in vitro* fertilisation
k *(in combination)*	kilo
k	rate constant for biodegradation
K	Kelvin
Ka	acid dissociation constant
Kb	base dissociation constant
K_{ads}	adsorption constant
K_{des}	apparent desorption coefficient
K_F	Freundlich distribution constant, indicating the relationship between de amount sorbed and equilibrium concentration in in water.
kg	kilogram
K_H	Henry´s Law constant (in atmosphere per cubic metre per mole)
K_{oc}	organic carbon adsorption coefficient
K_{om}	organic matter adsorption coefficient
K_{ow}	octanol-water partition coefficient
Kp	solid-water partition coefficient
kPa	kilopascal(s)
l, L	litre
LAN	local area network
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry
LC_{50}	lethal concentration, median
LCA	life cycle analysis
LC-MS-MS	liquid chromatography with tandem mass spectrometry

Stand. term / Abbreviation	**Explanation**
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
ln	natural logarithm
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
log	logarithm to the base 10
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar
µm	micrometre (micron)
MAC	maximum allowable concentration
MAK	maximum allowable concentration
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
MIC	minimum inhibitory concentration
min	minute(s)

Stand. term / Abbreviation	**Explanation**
MKC	minimum killing concentration
mL	millilitre
MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
MMAD	mass median aerodynamic diameter
mo	month(s)
MOE	margin of exposure
mol	mole(s)
MOS	margin of safety
mp	melting point
MRE	maximum residue expected
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MT	material test
MW	molecular weight
n.a.	not applicable
n-	normal (defining isomeric configuration)
n	number of observations
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometre
NMR	nuclear magnetic resonance
no, n°	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOED	no observed effect dose

Stand. term / Abbreviation	**Explanation**
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OEL	occupational exposure limit
OH	hydroxide
OJ	Official Journal
OM	organic matter content
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the acid dissociation constant
pKb	negative logarithm (to the base 10) of the base dissociation constant
PNEC	predicted no effect concentration (compartment to be added as subscript)
po	by mouth
POP	persistent organic pollutants
ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PPP	plant protection product
ppq	parts per quadrillion (10^{-24})
ppt	parts per trillion (10^{-12})
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	product type
PT(CEN)	project team CEN
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QA	quality assurance
QAU	quality assurance unit
(Q)SAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RA	risk assessment
RBC	red blood cell
REI	restricted entry interval
RENI	Registry Nomenclature Information System
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL_{50}	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase

Stand. term / Abbreviation	**Explanation**
rpm	revolutions per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
S	solubility
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SCAS	semi-continous activated sludge
SCTER	smallest chronic toxicity exposure ratio (TER)
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
S/L	short term to long term ratio
SMEs	small and medium sized enterprises
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STER	smallest toxicity exposure ratio (TER)
STMR	supervised trials median residue
STP	sewage treatment plant
t	tonne(s) (metric ton)
$t_{½}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxine
T_{25}	tumorigenic dose that causes tumours in 25 % of the test animals
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TG	technical guideline, technical group
TGD	Technical guidance document
TID	thermionic detector, alkali flame detector
TDR	time domain reflectrometry
TER	toxicity exposure ratio
TER_I	toxicity exposure ratio for initial exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TNsG	technical notes for guidance
TOC	total organic carbon
Tremcard	transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)

Stand. term / Abbreviation	**Explanation**
TTC	2,3,5-triphenylterazoliumchloride testing method
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UR	unit risk
UV	ultraviolet
UVC	unknown or variable composition, complex reaction products
UVCB	undefined or variable composition, complex reaction products in biological material
v/v	volume ratio (volume per volume)

Stand. term / Abbreviation	**Explanation**
vis	visible
WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

Abbreviations of Organisations and Publications

Abbreviation	**Explanation**
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
BBA	German Federal Agency of Agriculture and Forestry
CA(S)	Chemical Abstracts (System)
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Food
CE	Council of Europe

Abbreviation	**Explanation**
CEC	Commission of the European Communities
CEFIC	European Chemical Industry Council
CEN	European Committee for Normalisation
CEPE	European Committee for Paints and Inks
CIPAC	Collaborative International Pesticides Analytical Council Ltd
CMA	Chemicals Manufacturers Association
COREPER	Comite des Representants Permanents
COST	European Co-operation in the field of Scientific and Technical Research
DG	Directorate General
DIN	German Institute for Standardisation
EC	European Commission
ECB	European Chemicals Bureau
ECCO	European Commission Co-ordination

Abbreviation	**Explanation**
ECDIN	Environmental Chemicals Data and Information Network of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EEC	European Economic Community
EHC	Environmental Health Criteria
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre
EPA	Environmental Protection Agency
EPAS	European Producers of Antimicrobial Substances
EPFP	European Producers of Formulated Preservatives
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organization
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
EWMP	European Wood Preservation Manufacturers
FAO	Food and Agriculture Organization of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (now known as GCPF)
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory
GEMS	Global Environmental Monitoring System
GRIN	Germplasm Resources Information Network
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
ICBP	International Council for Bird Preservation
ICCA	International Council of Chemical Associations
ICES	International Council for the Exploration of the Seas
ILO	International Labour Organization
IMO	International Maritime Organisation
IOBC	International Organization for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
ISCO	International Soil Conservation Organization
ISO	International Organization for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JECFA FAO/WHO	Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the

Abbreviation	**Explanation**
	WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
MITI	Ministry of International Trade and Industry, Japan
NATO	North Atlantic Treaty Organization
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Center for Toxicological Research (USA)
NGO	non-governmental organisation
NTP	National Toxicology Program (USA)
OECD	Organization for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
OPPTS	Office of Prevention, Pesticides and Toxic Substances (US EPA)
OSPAR	Oslo Paris Convention (Convention for the Protection of the Marine Environment of the North-East Atlantic)
PAN	Pesticide Action Network
RIVM	Netherlands National Institute of Public Health and Environmental Protection
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SETAC	Society of Environmental Toxicology and Chemistry
SI	Système International d'Unitès
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UBA	German Environmental Protection Agency
UN	United Nations
UNEP	United Nations Environment Programme
WFP	World Food Programme
WHO	World Health Organization
WPRS	West Palearctic Regional Section
WTO	World Trade Organization
WWF	World Wildlife Fund